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98th Congress, 2d Session - - - - - House Report 98-1147

**PROBLEMS PLAGUE THE
ENVIRONMENTAL PROTECTION AGENCY'S
PESTICIDE REGISTRATION ACTIVITIES**

SIXTY-THIRD REPORT

**BY THE
COMMITTEE ON GOVERNMENT
OPERATIONS**



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OCTOBER 5, 1984.—Committed to the Committee of the Whole House on
the State of the Union and ordered to be printed

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(II)

Hon. THOMAS J.
Speaker of the
Washington, D

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
Washington, DC, October 5, 1984.

Hon. THOMAS P. O'NEILL, Jr.,
Speaker of the House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Government Operations, I submit herewith the committee's sixty-third report to the 98th Congress. The committee's report is based on a study made by its Environment, Energy, and Natural Resources Subcommittee.

JACK BROOKS, *Chairman.*

(III)

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98TH CONGRESS }
2d Session }

HOUSE OF REPRESENTATIVES

{ REPORT
98-1147

PROBLEMS PLAGUE THE ENVIRONMENTAL PROTECTION AGENCY'S PESTICIDE REGISTRATION ACTIVITIES

OCTOBER 5, 1984.—Committed to the Committee of the Whole House on the State of
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Mr. BROOKS, from the Committee on Government Operations,
submitted the following

SIXTY-THIRD REPORT

BASED ON A STUDY BY THE ENVIRONMENT, ENERGY, AND NATURAL
RESOURCES SUBCOMMITTEE

On September 25, 1984, the Committee on Government Operations approved and adopted a report entitled "Problems Plague the Environmental Protection Agency's Pesticide Registration Activities." The chairman was directed to transmit a copy to the Speaker of the House.

I. INTRODUCTION

In 1983 and 1984, the Subcommittee on Environment, Energy, and Natural Resources conducted a comprehensive review of the Environmental Protection Agency's pesticide registration activities.

The review was prompted by several events which pointed to serious problems in EPA's pesticide registration programs. For example, officials of one of the largest independent laboratories used by the pesticide industry to perform animal studies in support of pesticide registration applications (Industrial Biotest Laboratories) were indicted and convicted for falsifying data submitted to EPA in support of a pesticide registration application. Subsequently EPA did a review which showed that nearly 2,000 tests performed by the same laboratory on over 200 pesticides were included in other approved pesticide registrations, although it was not known whether these data were also falsified or whether they were crucial to the decision to approve the registrations.

In addition, a civil suit had been filed by the Natural Resources Defense Council seeking to overturn EPA procedures for pesticide

regulation and virtually every registration issued over a 14 month period alleging that the standards had been set unlawfully in closed-door meetings with the chemical industry.

These events raised serious questions as to whether EPA had been administering the pesticide registration program and utilizing its resources in a manner that would provide the fullest possible protection of public health. The purpose of the Subcommittee review was to evaluate the adequacy of a number of EPA's pesticide regulation activities, including (1) progress toward completing Rebuttable Presumption Against Registration actions against potentially unsafe pesticides, (2) status of the Congressionally mandated program to reregister older (pre-1972) pesticides to assure that they meet current safety standards, (3) adequacy of procedures for granting and monitoring emergency exemptions for unregistered uses of pesticides, and (4) the quality of the data being submitted in support of current pesticide registration applications and its review by EPA.

The Subcommittee began its study in June, 1983, and held public hearings on September 26, 1983 and June 7, 1984, receiving testimony from the following witnesses:

(1) Dr. John A. Moore, Assistant EPA Administrator for Pesticides and Toxic Substances; Dr. Richard N. Hill, Science Advisor, Office of Assistant EPA Administrator for Pesticides and Toxic Substances; Dr. Edwin L. Johnson, Director, Office of Pesticide Programs; Mr. Richard J. Johnson, Project Manager, Registration Division, Office of Pesticide Programs; and Dr. Stuart Cohen, Chemist, Hazard Evaluation Division, Office of Pesticide Programs.

(2) Dr. John A. Todhunter, Former Assistant EPA Administrator for Pesticides and Toxic Substances.

(3) Ms. Jackie Warren, Staff Attorney, Natural Resources Defense Council.

On March 5 and 6, 1984, the Subcommittee also held a joint hearing with the Intergovernmental Relations and Human Resources Subcommittee on government regulation of the pesticide ethylene dibromide (EDB), receiving testimony from the following witnesses:

(1) Hon. William D. Ruckelshaus, EPA Administrator, accompanied by Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances; Dr. Edwin L. Johnson, Director, Office of Pesticide Programs; and Mr. Richard J. Johnson, EDB Review Team Leader.

(2) Dr. Mark Novitch, Acting Commissioner, Food and Drug Administration, Public Health Service, Department of Health and Human Services, accompanied by Joseph Paul Hile, Associate Commissioner for Regulatory Affairs; Thomas Scarlett, Chief Counsel, Food and Drug Division; Sanford A. Miller, Director, Bureau of Foods; and John R. Wessell, Scientific Coordinator, Office of the Associate Commissioner for Regulatory Affairs.

(3) Kenneth A. Giles, Administrator, Federal Grain Inspection Service, U.S. Department of Agriculture, accompanied by William F. Helms, Associate Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection

Service; and Dr. I. of the Agriculture

(4) Dr. Linda Health, State of I

(5) Dr. Stephen Health and Rehal

(6) Dr. Bailus Commonwealth o

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Service; and Dr. Richard Parry, Assistant to the Administrator of the Agricultural Research Service.

(4) Dr. Linda Randolph, Director of the Office of Public Health, State of New York.

(5) Dr. Stephen H. King, State Health Officer, Department of Health and Rehabilitation Services, State of Florida.

(6) Dr. Bailus Walker, Jr., Commissioner of Public Health, Commonwealth of Massachusetts.

In the course of its investigation, the Subcommittee staff reviewed pesticide registration files, correspondence, intra- and inter-agency memoranda, reports, studies, summaries, and official hearing docket files at EPA headquarters in Washington, DC. The staff also met with regulatory staff of EPA and other Federal and state agencies, environmental groups, pesticide industry representatives, and other interested individuals in the private sector.

II. BACKGROUND

The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, (7 U.S.C. Section 136 et seq.) provides for the regulation of all pesticide products by the Environmental Protection Agency (EPA). The act requires that products be registered by EPA before they may be sold or distributed in interstate commerce. In order to register a pesticide, EPA must determine that its use will not result in "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits . . ." If a pesticide is to be sold and used in the production or storage of crops, meat, milk, or eggs, EPA also establishes a tolerance (maximum allowable limit of pesticide residue) or an exemption from the requirement of a tolerance, for each individual crop or edible animal product on which it will be used or may be present because of another approved use.

Section 6(a)(2) of the act requires that registrants notify EPA of any additional factual information regarding unreasonable adverse effects on the environment from a pesticide which occur after registration. Section 6(b) of the Act authorizes EPA to issue a notice of intent to cancel the registration or to change a pesticide's classification, if it appears that the pesticide or its labeling does not comply with the provisions of the Act or may cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice. Rebuttable Presumption Against Registration (RPAR) or "special review" is the process by which EPA gathers risk and benefit information about pesticides which appear to pose risks to health or to the environment. RPAR regulations (40 CFR 162.11) describe various risk criteria and provide that an RPAR shall be initiated if EPA determines that any of the risk criteria have been met.

Once a notice of RPAR is published, registrants, applicants, and other interested persons may submit evidence in rebuttal or in support of the presumption. If the presumptions of risk are not rebutted, the evidence regarding the benefits from use of the pesticide submitted to or gathered by EPA is evaluated and considered along with the risk information. EPA analyzes various risk reduction methods and their costs and then determines whether or not the

potential risks of a pesticide use may be outweighed by its benefits. If a balance between risks and benefits cannot be reached for a specific use, EPA can cancel the registration for that use.

The 1972 amendments to FIFRA required that EPA review and reregister previously registered pesticide products. For reregistration, pesticide companies were to supply animal test data to show whether their products had the potential for causing tumors, birth defects, adverse reproductive effects or other harmful chronic effects, as well as data on exposure to pesticides which might affect fish, mammals, or birds. The re-registration program involves at least 50,000 pesticide registrations which had been approved over the preceding 30 years. Congress initially mandated that this task be completed by October 21, 1976; however, it subsequently extended the completion date until October 21, 1977 and later abolished the deadline altogether.

The Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 301, et seq.) authorizes the establishment of tolerances and exemptions from tolerances for residues of pesticide chemicals in or on raw agricultural commodities (Section 408) and the promulgation of food additive regulations for pesticide residues in processed food (Section 409). Without such tolerances, exemptions from tolerances, or food additive approval, a food is considered adulterated under Section 402 of the Act and may not legally move in interstate commerce. Under the Reorganization Plan which established EPA in 1970, the authority to set tolerances for pesticide chemicals in raw agricultural commodities and processed food under Section 408 and 409 of the FFDCA was transferred from the Food and Drug Administration (FDA) to EPA.

A food additive regulation under Section 409 may not be established for a carcinogenic substance because of the so-called "Delaney Clause" (Section 409(c)(3)(A)), which provides that no additive is deemed safe if it induces cancer when ingested by man or animal. However, the Delaney Clause does not apply to the issuance of tolerances for pesticides on raw agricultural commodities pursuant to Section 408 of the FFDCA.

FDA has the responsibility for enforcing the tolerances established by EPA, and may seize an adulterated commodity or processed food if the pesticide residues exceed the tolerance, approved food additive level, or an established action level. (Action level refers to the level of contamination at which a food will be deemed to be adulterated in situations in which a tolerance or exemption has not been established or has been revoked. In cases where a tolerance or food additive approval does not exist to cover residues resulting from the use of a pesticide, action levels may be set by FDA based on the recommendations of EPA.)

The Secretary of Agriculture is required to certify the usefulness of a pesticide during the tolerance setting process. EPA is also required to obtain the comments of the Secretary of Agriculture before an RPAR action can be finalized. The Department's Animal and Plant Health Inspection Service (APHIS) is responsible for imposing quarantines to protect against the importation or spread of pests including the development of manuals prescribing use of pesticides to achieve eradication. The Agricultural Research Service (ARS) provides research data to APHIS on (1) residue levels in

treated commodities as sterilization of pes

III. REBUTTAL

The Rebuttable Process was intended to show whether to remove a or to restrict its use represents a potentia

In 1975, EPA issued which, among other health and environmental reasonable, such as Since 1976, EPA has tial health hazards. 1 68 cases.

Disposition

Resolved prior to RPAR....
Insufficient evidence of RI
Voluntarily cancelled before
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The 36 RPAR actions
1981. The following
year.

Year

1976.....
1977.....
1978.....

As of the Subcommittee RPAR's had been co Administrator Moore pected to be completed ber 26, 1983 hearing, Pesticide Programs, ferred the term "sp ing." ¹ EPA initiate (March 1984) and at that 4 more special the June 7 hearing. ated special reviews daminozide (Alar).

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III. REBUTTABLE PRESUMPTION AGAINST REGISTRATION

The Rebuttable Presumption Against Registration (RPAR) process was intended to provide for an expedited decision by EPA on whether to remove a registered pesticide product from the market, or to restrict its use, whenever new information indicates that it represents a potential hazard to public health or the environment.

A. RPAR ACTIVITY

In 1975, EPA issued final regulations for the RPAR process which, among other things, established criteria for identifying the health and environmental effects that it would presume to be unreasonable, such as cancer, birth defects and genetic mutations. Since 1976, EPA has singled out 68 registered pesticides as potential health hazards. The following table shows the disposition of the 68 cases.

Number of pesticides

Disposition	
Resolved prior to RPAR.....	4
Insufficient evidence of RPAR hazard.....	11
Voluntarily cancelled before RPAR.....	17
RPAR initiated.....	36

The 36 RPAR actions were initiated between March 1976 and April 1981. The following table shows the number of RPAR actions by year.

RPAR's

Year	Number	Year	Number
1976.....	7	1979.....	3
1977.....	16	1980.....	2
1978.....	7	1981.....	1

As of the Subcommittee's hearing on June 7, 1984, 26 of the RPAR's had been completed and ten were still ongoing. Assistant Administrator Moore testified that five of the ten RPAR's were expected to be completed during fiscal year 1984. During the September 26, 1983 hearing, Edwin Johnson, then Director of the Office of Pesticide Programs, stated that instead of RPAR, EPA now preferred the term "special review" because it was "less threatening."¹ EPA initiated a special review of the pesticides dicofol (March 1984) and amitrole (April 1984) and Dr. Moore indicated that 4 more special reviews would be initiated within 60 days of the June 7 hearing. However, as of mid-September, EPA had initiated special reviews of only two additional pesticides—aldicarb and daminozide (Alar).

¹ The term "RPAR" and "special review" are used interchangeably in this report.

B. LACK OF RPAR'S DURING PERIOD 1981 TO 1984

EPA initiated no RPAR's at all during the period April 1981 to March 1984. Dr. Edwin Johnson testified that one reason for the hiatus in RPAR actions was that during the period 1976-1977 EPA issued more RPAR actions than it could have conceivably handled and it was just now finishing up those actions. He also testified that a Congressional amendment in 1980, which required that EPA determine that there was sufficient risk as to cause a prudent person concern before initiating an RPAR, probably deterred the agency from initiating some RPAR's. However, the Subcommittee's investigation also revealed that the special pesticides review section, which handled RPAR actions, was demoted from division to branch status and the number of people available to work on such actions dropped from 85-100 people in 1980 to just 22 in 1984.

In addition, the Subcommittee found that EPA changed its procedures with respect to initiating RPAR actions in apparent violation of its own regulations which require the agency to begin such an action as soon as one of the risk criteria mentioned in its regulations is met or exceeded. Testimony presented at the June 7, 1984 hearing indicated that EPA was delaying initiation of RPAR actions until a complete Registration Standard had been issued for a pesticide. The following exchange took place after Mr. Johnson was asked why EPA did not initiate an RPAR on dicofol after one of the risk criteria had been met.

Mr. JOHNSON. I just explained that the reason we did not initiate an RPAR is because we had changed our procedure so that when we were reviewing a chemical and we came on an RPAR trigger, we were not going to RPAR immediately upon finding it but rather would finish our complete review of the chemical so that we would know what all its problems were, not just the one we happen to find.

Mr. GRAY. Meaning you were going to do a complete risk/benefit analysis; correct?

Mr. JOHNSON. No.

Mr. GRAY. Well, then what do you mean by that?

Mr. JOHNSON. There are a lot of other effects that a chemical may cause. There are also data gaps that involve other things besides the potential environmental impact of the chemical. So in the registration standards program we don't look only for triggers; we look at the whole toxicological picture of the chemical and the degree to which we know or don't know that toxicological picture.

When we conclude that review, we may have an effect that says that we ought to RPAR the chemical, but we also have a number of other questions, other data, and in the past when we had gotten into an RPAR, based only on one study and one effect, we found that after we concluded the RPAR we really hadn't reviewed the chemical, and we had to go back and spend a lot of time reviewing all the other aspects of the chemical, if in fact it weren't canceled.

Mr. GRAY. I guess the problem, Dr. Johnson, is that it looks like you are beginning to blur the line here between what is just a registration standard and an RPAR. You

have regulations an RPAR process

Now you seem when you have c ahead and do all tion standard fo RPAR process.

The question RPAR? As we h the RPAR proces because of the se

Are you telling that you can look pesticide? Is that

Mr. JOHNSON. 7

Once we have tion standard th ably takes us ab complete that action trigger, but we k so we can deal wi

Number two, v and if the data b chemical off the i in reaching a res

Mr. GRAY. I gu you need? It only Why do you nee trigger, you have potential problem

To say that we problems seems t of having an RPA

Mr. JOHNSON. 1 at it, and we we point of view. We process which yo many times. In t that one thing v know more about the issues better ess.

We are talking you say a year a past experience, i to muddle throug

Mr. SYNAR. The

C. WHY THE RPAR PROCESS IS NOT AN ACTION REG

One of the RPAR at Subcommittee's invest

1 TO 1984

period April 1981 to one reason for the period 1976-1977 EPA conceivably handled s. He also testified required that EPA o cause a prudent bably deterred the the Subcommittee's sticides review sec- ed from division to le to work on such st 22 in 1984.

changed its proce- apparent violation y to begin such an ioned in its regula- at the June 7, 1984 ation of RPAR ac- d been issued for a r Mr. Johnson was dicofol after one of

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have regulations that set certain triggers that are to start an RPAR process . . . cancer, mutagenic effects, and so on.

Now you seem to be saying that even when one of those, when you have one of those triggers, you are going to go ahead and do all the total review necessary for a registration standard for that product before you initiate the RPAR process.

The question is: Doesn't that defeat the purpose of RPAR? As we have understood it and have discussed it, the RPAR process is to provide for an expedited decision because of the seriousness of certain potential side effects.

Are you telling us that you are not going to do that so that you can look at all other potential problems with that pesticide? Is that what you are saying?

Mr. JOHNSON. That is part of the answer.

Once we have reached the determination in a registration standard that we have hit an RPAR trigger, it probably takes us about another six months to a year to complete that action. At that time we know not only of the trigger, but we know whether there are any other triggers so we can deal with them all at once.

Number two, we can ask the company for all the data, and if the data bill is too high, the company may take the chemical off the market, and, therefore, we have succeeded in reaching a resolution.

Mr. GRAY. I guess the question is: How many triggers do you need? It only takes one to kill somebody; doesn't it? Why do you need more than one trigger? If you have a trigger, you have a trigger, it seems to me, and you have a potential problem.

To say that we want to find out all the other potential problems seems to be kind of defeating the whole purpose of having an RPAR process.

Mr. JOHNSON. I think there are several ways of looking at it, and we were looking at it partly from an efficiency point of view. We had seen the inefficiencies with the old process which you and the Chairman have commented on many times. In trying to improve the process, it seemed that one thing which improved it tremendously was to know more about the chemical and be able to deal with the issues better and that that should speed up the process.

We are talking about finishing dicofol in a year, so if you say a year ago we should have RPARED it, given our past experience, it might have taken us three to four years to muddle through without the data that we needed.

Mr. SYNAR. That is an understatement.

C. WHY THE RPAR PROCESS IS INEFFECTIVE—A CASE STUDY OF EPA'S ACTION REGARDING ETHYLENE DIBROMIDE (EDB)

One of the RPAR actions which was finally completed during the Subcommittee's investigation involved the pesticide EDB. EPA's ex-

EDB is the common name for 1,2-dibromoethane, a colorless, non-flammable liquid. The three major producers of EDB were DOW Chemical, Ethyl Corporation, and Great Lakes Chemical Company. EDB's major use for many years has been as a gasoline additive to prevent lead deposits in engines using leaded gasoline. In addition, pesticidal use of EDB was about 11-15 million pounds per year. Fifty-three registrants had obtained a total of 122 registrations for EDB products. Ninety percent of the pesticidal use of EDB products was for preplanting fumigation by soil injection on food and non-food crops including vegetables, fruits, grains, peanuts, cotton and tobacco. Other major registered pesticidal uses of EDB were post-harvest commodity fumigation for grains, fruits and vegetables (including various State, Federal or international quarantine programs on citrus, fruits, nuts, and vegetables); and fumigation of grain milling machinery and flour mills to control insect infestations in milling remnants and other processed milled products. Minor uses of EDB products included controls for wax moths in beehive supers; mountain pine bark beetles in Western states; drywood and subterranean termites in structural pest control operations; clothes moths, dermestid beetles, and similar pests in fumigation vaults; and Japanese beetles in the soil of balled ornamental trees and shrubs under the USDA quarantine program.

On October 16, 1974, the National Cancer Institute (NCI) issued a "Memorandum of Alert" describing a preliminary finding that EDB produced cancer in mice and rats; this finding was confirmed in a final NCI report in 1975. In November 1975, EPA's Special Pesticide Review Division accepted EDB as a candidate for the RPAR process. In addition to the NCI report, other evidence for the referral included studies showing EDB to be mutagenic and capable of producing adverse reproductive effects in several species of animals. On September 7, 1977, EPA's Carcinogen Assessment Group issued a preliminary risk assessment which stated that there was strong evidence that EDB was likely to be carcinogenic (cancer-causing) to man.

On December 14, 1977, EPA Issued an RPAR notice in the form of Position Document 1 (PD-1), based on the risks to man of oncogenicity (tumors), mutagenicity, and adverse reproductive effects as a result of pesticidal exposure to EDB. After reviewing responses to the PD-1, EPA issued its PD 2/3 on December 10, 1980. The PD-2/3 contained the rebuttal assessment, risk analysis, benefits analysis, risk/benefit synthesis, and proposed the following actions:

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On April 6, 1988, comments on EPA's continued use of fumigation as a decision on several occasions. However, the Secretariat for fumigation of food felt there was insufficient gamma irradiation quarantine fumiga-

On April 22, 1988, the EPA submitted its report on the testing of fumigants. The report concluded that the use of methyl bromide for spot fumigation of stored grain was not justified. The report also stated that the use of methyl bromide for fumigation of stored grain was not justified. The report also stated that the use of methyl bromide for fumigation of stored grain was not justified.

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Cancellation of registrations for post-harvest fumigation of citrus, tropical fruits, and vegetables *effective July 1, 1983*, in order to allow time for the development and implementation of alternatives.

Continuing registration for the remaining uses with requirements for protective clothing and other low-cost measures designed to reduce applicator exposure.

On April 22, 1981, EPA's FIFRA Scientific Advisory Panel (SAP) submitted its report on EPA's proposed regulatory actions regarding products containing EDB. The Panel concurred with the proposals to cancel registrations for fumigation of stored grain and spot fumigation of milling machinery, until such time as convincing evidence existed that such uses posed little or no hazard to consumers of bakery products. However, the Panel differed with EPA's position that EDB use on citrus should be phased out by July 1983, and proposed that this use be retained with requirements for additional protective measures to reduce worker exposure. Despite the apparent completion of the RPAR review process, no final EPA action was forthcoming.

The Subcommittee's hearing on September 26, 1983, focused on EPA's delay in taking final action on EDB. The hearing showed that economic and political considerations, as well as bureaucratic footdragging and inefficiencies caused most of the delay, rather than legitimate scientific disputes about the dangers of EDB.

With regard to the length of time that an RPAR action can drag on, the hearing revealed that neither FIFRA nor EPA regulations

establish an overall time limit for the completion of an RPAR. Although persons who wish to comment on RPAR actions are given specific deadlines for responses, there are no established deadlines for EPA actions. When Dr. Edwin Johnson was asked if it would be a good idea to have deadlines for EPA's RPAR actions, he said that as manager he would normally say no, but that:

I guess, on the other hand, given our experience in attempting to shorten the RPAR process, which we have been actively trying to do for the last 5 years, some statutory deadlines may well enable the agency or force the agency to act more quickly and to give these higher priority.

So, given my experience, I think there might be some benefit in this particular case, although generally I am not in favor of those kinds of deadlines.²

Subsequent to the issuance of the PD-2/3, Dr. Todhunter and other EPA officials had numerous contacts with registrants of EDB products, other Federal and State agencies, and affected user groups such as the milling industry and citrus industry. When meetings were involved, EPA officials usually did not make memoranda of the meeting. Without such memoranda, Congress and the public remain ignorant of who was present, what occurred, what information was presented, and whether any decisions were made on the basis of the meeting. Ms. Jackie Warren of the Natural Resources Defense Council was critical of such off the record meetings, as alleged in the following quote from her testimony:

Consistent meetings have been held between EPA and the registrants to evaluate the risks and the benefits of suspect pesticides and decide what ought to be done about them. These meetings are entirely out of the public view—under a statute that intended those questions to be resolved in a public forum—the decision whether the RPAR should be triggered, whether it should be terminated, what a registration standard should look like.

The agency claims that there is public input into these decisions. It is minimal, and as the chairman noted earlier today, all the important decisions are made in private meetings where the public is not present.³

Throughout the regulatory deliberations on EDB, EPA officials were especially solicitous concerning the potential effect of their proposals on the Florida citrus industry. There were numerous meetings between representatives of the Florida citrus industry and EPA officials at which the industry representatives expressed their concerns about the economic consequences of an EPA decision to phase out the use of EDB on citrus. The citrus industry maintained that if EDB were banned they would lose their share of the Japanese market and that there was no effective alternative to EDB.

² Hearings, September 26, 1983.

³ Hearings, September 26, 1983.

On May 26, 1982, Dr. Todhunter met with representatives regarding the PD-4 for EDB. Discussions were made at the meeting because Dr. Todhunter conveyed at the meeting. However, on May 27, 1982, Dr. Todhunter wrote Dr. Todhunter that:

I appreciate your office so promptly agreed to delay issuance of the earliest, pending myself and Senator

Dr. Todhunter testified "any such thing." No May 27, 1982, Congressman Anne M. Gorsuch

I understand that between Dr. Todhunter and the Florida fruit industry to delay issuing a decision on EDB starting in

EPA subsequently from July 1983 to July

5. Potential conflict of

In February 1983, EPA wanted to advise the agency to the phased cancellation of citrus fruit. Dr. Edwin Johnson of the idea of getting a decision. Dr. Todhunter approved the action form showed the selling service involving international trade, and was including farm and citrus industry. The citrus industry comprised of private citizens. Dr. Lerch testified that Mr. Lerch Government on several Japanese marketing and commercial channels. Dr. Lerch his connection with the citrus industry. Dr. Lerch testified that no conflict of interest existed.

The Subcommittee held a hearing with EPA. The hearing was an annual retainer to the citrus industry on agricultural issues. The hearing was another hearing⁶ before

⁴ Hearings, September 26, 1983.

⁵ Hearings, September 26, 1983.

⁶ Financial Disclosure and Conflict of Interest, November 14, 1983.

tion of an RPAR. All AR actions are given established deadlines. I was asked if it would be possible to take actions, he said that it is:

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On May 26, 1982, Dr. Todhunter, Dr. Johnson, and other EPA officials met with representatives of the Florida citrus industry regarding the PD-4 for EDB. Dr. Todhunter testified that no decisions were made at the meeting and no official record was kept of the meeting because no important or significant information was conveyed at the meeting nor any conclusion reached afterward. However, on May 27, 1982, Congressman Andy Ireland of Florida wrote Dr. Todhunter that:

I appreciate your having Dr. Wells on your staff call my office so promptly this morning to confirm that you have agreed to delay issuing the rule on EDB until July, at the earliest, pending consultations with OSHA, and with myself and Senators Chiles and Hawkins.⁴

Dr. Todhunter testified that he did not tell Congressman Ireland "any such thing." Nonetheless, the Subcommittee found that on May 27, 1982, Congressman Ireland also wrote then EPA Administrator Anne M. Gorsuch that:

I understand that on the basis of a meeting yesterday between Dr. Todhunter of your staff and representatives of the Florida fruit and vegetable industry, EPA has agreed to delay issuing a rule which would have banned the use of EDB starting in 1983.⁵

EPA subsequently revised its proposed regulation to postpone from July 1983 to July 1985 the phase out of EDB on citrus.

5. Potential conflict of interest

In February 1983, EPA hired Mr. Donald G. Lerch as a consultant to advise the agency on what the Japanese reaction might be to the phased cancellation of EDB as a quarantine fumigant on citrus fruit. Dr. Edwin Johnson, Director, OPP, apparently thought of the idea of getting a consultant and suggested Mr. Lerch and Dr. Todhunter approved the hiring of Mr. Lerch. Mr. Lerch's personnel action form showed that his firm "provides a wide range of counseling service involving government regulations, marketing, international trade, and works with virtually all agribusiness interests, including farm and commodity organizations, and trade associations comprised of private companies." Dr. Edwin Johnson also testified that Mr. Lerch had acted as representative for the Japanese Government on several issues and was knowledgeable about the Japanese marketing system and with the people in the government and commercial channels. Dr. Johnson said he discussed with Mr. Lerch his connection with the Japanese government and determined that no conflict of interest existed.

The Subcommittee obtained and reviewed the financial statement filed with EPA by Mr. Lerch, which revealed that he was on an annual retainer to the Japanese Government to counsel them on agricultural issues at the same time he was hired by EPA. At another hearing⁶ before the Subcommittee, Dr. Johnson testified

⁴ Hearings, September 26, 1983.

⁵ Hearings, September 26, 1983.

⁶ Financial Disclosure and Conflict of Interest Prevention Program at the Environmental Protection Agency, November 14, 1983.

that he did not see Mr. Lerch's financial statement because he was out of the country when it was submitted and that the review was handled by his deputy. Mr. Donnell Nantkes, EPA's Alternate Agency Ethics Official, testified that Mr. Johnson's deputy did in fact discuss Mr. Lerch's case with him, but that he had no further recollection of the details of their discussion.

In March 1983, Mr. Lerch submitted his report to EPA which concluded that there would be some high probability of an adverse reaction by Japan to the elimination of EDB for citrus fumigation and that the Japanese would not accept irradiation as an alternative treatment. By letter dated May 18, 1982, Mr. Jacek S. Sivinski of another consulting firm, CH-2M Hill, differed sharply with Mr. Lerch's conclusion regarding irradiation of citrus for the Japanese market. Mr. Sivinski stated:

The report by Mr. Lerch I also find disconcerting because it appears that he was speaking to people who did not know what the current state of activity in Japan was. For instance he states that there was only a 30,000-ton lot of potatoes processed in 1973. That is certainly not the case; I visited the potato irradiator on Hokkaido last year and it is going full bore now and has in the past. In fact, a document which has just now been prepared by the IAEA [International Atomic Energy Agency] and the WHO [World Health Organization] with a new proposal for phase 2 of the Asian Regional Cooperative Project on Food Irradiation states on page 3 that Japan was the first country in the world to commercially irradiate food on an industrial scale.⁷

In any event, Dr. Johnson testified that no changes were made to the prepared PD-4 as a result of Mr. Lerch's study.

Dr. Todhunter left EPA on March 25, 1983 and for a time worked as a self-employed consultant doing work for the National Agricultural Chemicals Association and the American Council on Science and Health. However, in December 1983 a press release announced the appointment of Dr. Todhunter as a partner of Mr. Lerch in the formation of Lerch Agrichemical Services. According to the press release, the action was taken in order to "expand the firm's capability in handling problems related to registration and use of crops and food chemicals for both users and producers."⁸

6. Ground water contamination situations arise during regulatory delay

Although EPA was delaying its proposed regulations on EDB primarily because of questions about the quarantine treatment of citrus fruits, it did not sever that relatively small-volume usage from the regulatory package and proceed to act on the other uses. In the interim, serious problems surfaced with respect to the major (90 percent) usage of EDB as a soil fumigant. On June 14, 1982, a representative of the Dow Chemical Company had informed EPA that EDB had been detected in irrigation well water in Georgia. In

June 1983, the California reported finding EDB in the States of Hawaii and ground water. The States that 100 out of 400 10,000 people, were at the time of the Subcommittee the number of EDB contaminated with 3,000 wells still

Most of the contamination amounts of EDB far exceeding citrus grove nematodes. Although proved EPA labeling of Agriculture's Animal (APHIS) manual for APHIS manuals are and, if not, the EPA manual directives, A this fact to the Florida Department ignored it. The Administrator of the Florida Department that he on July 29, 1982 and the Department would requirements. On September Agriculture banned the

7. Interim EPA regulations

On September 30, 1983, EPA issued the interim regulations on the elimination of EDB from the RPA.

Ordered an emergency plant soil fumigation

Cancelled the emergency and for fumigation requiring additional agency suspension

Cancelled the emergency fumigant on citrus, to be effective on September 1, 1984, in order to change to alternative

Cancelled the emergency Continued the emergency

Continued the emergency measures for additional use data.

The emergency suspension banned any further suspension actions were suspended about 2 years—and continued during the emergency prolonged all proposed ca

⁷ Hearings, September 26, 1983.

⁸ Press Release available for review in Subcommittee offices.

⁹ Hearings on Groundwater,

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ulations on EDB pri- intine treatment of small-volume usage t on the other uses. respect to the major On June 14, 1982, a had informed EPA water in Georgia. In

June 1983, the California Department of Food and Agriculture reported finding EDB in water wells in that State. Subsequently, the States of Hawaii and Florida also reported EDB contamination of ground water. The situation in Florida was particularly acute in that 100 out of 400 wells sampled, including 4 wells serving over 10,000 people, were found to contain unsafe levels of EDB. By the time of the Subcommittee's April 11, 1984 hearing on groundwater, the number of EDB contaminated wells in Florida had reached 618, with 3,000 wells still to be sampled.⁹

Most of the contamination in Florida was due to the injection of amounts of EDB far in excess of EPA labeling, into the soil surrounding citrus groves in the central part of the State to control nematodes. Although the treatment was not in accordance with approved EPA labeling it was done pursuant to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) manual for quarantine control of nematodes. Although APHIS manuals are supposed to be consistent with EPA labeling and, if not, the EPA label instructions have precedence over the manual directives, APHIS either failed to properly communicate this fact to the Florida Department of Agriculture or the latter Department ignored it. In any event, on August 23, 1983, the Commissioner of the Florida Department of Agriculture informed the EPA Administrator that he had terminated use of EDB in citrus groves on July 29, 1982 and assured EPA that any future use of EDB by the Department would be in compliance with the label and Federal requirements. On September 19, 1983, the Florida Department of Agriculture banned the use of EDB as a soil fumigant.

7. Interim EPA regulatory actions

On September 30, 1983, four days after the Subcommittee's hearing, EPA issued the PD-4 on EDB which presented its final determination on the RPAR. In issuing the PD-4, EPA:

Ordered an emergency suspension of the use of EDB for pre-plant soil fumigation;

Cancelled the uses of EDB in spot fumigation of grain mills and for fumigation of stored grain and announced it was gathering additional information to determine whether an emergency suspension of these uses was also necessary;

Cancelled the use of EDB as a post-harvest quarantine fumigant on citrus, tropical fruits, and vegetables effective September 1, 1984, in order to allow the USDA and the industry time to change to alternative means of disinfestation;

Cancelled the use of EDB as a felled log fumigant; and

Continued the remaining minor uses of EDB with requirements for additional labeling, protective clothing, and submission of use data.

The emergency suspension order took effect immediately and banned any further soil injection use of EDB. However, the cancellation actions were subject to the appeal process—which can take about 2 years—and would allow disputed uses of the pesticide to continue during the appeal period. Registrants and/or users challenged all proposed cancellations of EDB.

⁹ Hearings on Groundwater, April 11, 1984.

Subsequent to EPA's actions, the State of Florida and other parties began discovering high levels of EDB residues in processed grain products. On December 9, 1983, the Florida Department of Agriculture began issuing stop-sale orders on all lots of products containing detectable levels of EDB—approximately 1 part per billion (ppb). On January 13, 1984, the EPA Administrator sent letters to the governors of all 50 states requesting any data the states had on food products contaminated by EDB. In response EPA received data from FDA, USDA, several states, the American Bakers Association and the Grocery Manufacturers Association.

On February 3, 1984, EPA announced the following additional actions against EDB:

Immediate emergency suspension of all uses of EDB to fumigate stored grains and grain milling equipment;

Issuance of guidelines for maximum permissible levels of EDB: 900 parts per billion (ppb) in raw grains, 150 ppb in processed grain products, and 30 ppb in ready-to-eat products;

Initiation of a rulemaking process to terminate the exemption from the tolerance requirements for EDB on grain products; and

Initiation of action to establish appropriate, federally enforceable, maximum residue levels for EDB.

EPA also said it was collecting additional data on the use of EDB as a fumigant on citrus and would announce its decision with respect to this use within a few weeks.

8. EPA's recommended maximum permissible levels caused problems for the States

Although there was variation among the states in terms of legal authority, manpower, funding, and technical resources available for enforcement of the recommended maximum permissible levels of EDB, EPA did not formally research and document the individual states' legal authorities and resources before announcing the guidelines. Thus, after EPA's announcement, some states followed their own rulemaking procedures to adopt limits while others relied on voluntary recalls of EDB products. Forty-two states and the District of Columbia adopted EPA's recommended levels, five states did not adopt any standards at all, and three states developed standards which were different from those recommended by EPA. In addition seven of the states which adopted EPA's recommendations for most products also established a detection-level standard for infant foods. As a result, there was no assurance that citizens of different states received equal protection, or that states which failed to adopt standards would not become dumping grounds for contaminated grain or products from states which did adopt standards.

During the March 5, 1984 joint hearing, public health officials from New York, Massachusetts, and Florida testified that they did not know what happened to EDB contaminated products which had been removed from the shelves of stores in their states and could not assure the Subcommittee that the products were not simply routed to other states.

Finally, by issuing such guidelines, EPA precluded some states from issuing more restrictive standards. In the latter cases, states

have so-called "no maximum" standards from adopting standards.

9. Failure to revoke the tolerance resulted in continued use

The reason EPA continued to allow EDB was that in 1956 such tolerances in the bread and baking processes EDB did, in fact, survive. EPA's action to revoke the tolerance was delayed.

In 1965 the United States issued a report recommending that no residue tolerance be set for EDB in bread and that there be no baking process. Following this recommendation, Dr. R. Johnson's baking study in April 1965 showed that EPA's tolerance of 1 ppb of EDB in bread and 30 to 40 ppb in other products was not justified. On September 23, 1965, EPA announced its decision to revoke the tolerance for EDB in bread.

EPA's PD 1 on EDB was issued in 1965. It contained experiments confirming that EDB survived in baked products. A chemist in EPA's research division testified that EDB survived in bread. This finding was included in the RPAR review for EDB from the pesticide committee's joint hearing. Mr. Richard Johnson

Mr. R. JOHNSON had thought that the tolerance would be put into effect. We put it into effect in 1980, got a strong reaction in 1981, and as far as I know then I felt the use of EDB was not a good way and that it was not a good idea.

Mr. WEISS. So the situation just remained the same.

Mr. R. JOHNSON that there was in fact no way.¹⁰

EPA's PD-2/3 dated March 1984. John Holder of EPA testified that in biscuits baked from 1965 to 1984 EDB was present. In a February 1984 hearing, Dr. Holder

¹⁰ Joint Hearings on EDB, N

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have so-called "no more stringent" clauses which prohibit them from adopting standards which are more restrictive than Federal standards.

9. Failure to revoke the exemption from pesticide tolerance requirement resulted in additional exposure to EDB

The reason EPA could not immediately propose tolerances for EDB was that in 1956 EDB treated grain had been exempted from such tolerances in the belief EDB was dissipated during the milling and baking processes. Despite numerous subsequent findings that EDB did, in fact, survive milling and baking, EPA did not take action to revoke the exemption until 1984.

In 1965 the United Nations Food and Agriculture Organization issued a report recommending that EDB be used only on the condition that no residue of the unchanged compound reach the consumer and that there be further investigation of the effect of processing and cooking on the residues of EDB in food. Pursuant to this recommendation, Dr. S.L. Wit and others published the results of a baking study in April 1969. Using a method of detection sensitive to 1 ppb of EDB they found 6 to 26 ppb of EDB in whole wheat bread and 30 to 40 ppb in white bread. The investigation also showed that EPA personnel were aware of the Wit study at least as of September 23, 1975 when they discussed it in an interagency meeting on EDB.

EPA's PD 1 on EDB also discusses the Wit study. Subsequent experiments confirming the existence of EDB residues in finished baked products were discussed in a December 1978 report by a chemist in EPA's residue chemistry branch. Despite the findings that EDB survived the baking process, EPA did not incorporate into the RPAR review process a revocation of the 1956 exemption for EDB from pesticide tolerance requirements. During the Subcommittee's joint hearings the following discussion took place after Mr. Richard Johnson was asked why EPA took no such action.

Mr. R. JOHNSON. Well, we would have, certainly if we had thought that the cancellation would not have gone into effect. We proposed to cancel that use in December of 1980, got a strong endorsement from the scientific panel in 1981, and as far as I was concerned as project manager then I felt the use was going to be canceled and out of the way and that any actions on tolerances would be irrelevant.

Mr. WEISS. So from 1977 to 1978 to the fall of 1983 the situation just remained static?

Mr. R. JOHNSON. I do not think so. I think you will see that there was information gathering and collection under-way.¹⁰

EPA's PD-2/3 dated December 1980 described a study by Dr. John Holder of EPA which showed EDB residues of up to 260 ppb in biscuits baked from flour being used in the Federal school lunch program. In a February 27, 1980 memorandum to Mr. Richard Johnson, Dr. Holder said, "I view it essential to procure data on

¹⁰ Joint Hearings on EDB, March 5, 1984.

the actual EDB residues in bread throughout the U.S. at various times in a production year." However, such data were not collected by EPA or FDA because OPP had decided to recommend the cancellation of such use of EDB and because there were questions regarding confirmation of the analytical method previously used to measure EDB in the biscuits.

10. Final regulatory action

On March 2, 1984, EPA announced interim tolerances for EDB in citrus fruits and papayas at 200 ppb, of which no more than 30 ppb could be in the edible portion of the fruit. Such tolerances were effective until September 1, 1984. Afterwards any detectable residues of EDB in citrus fruits and papayas would render the commodities adulterated and subject to enforcement action by FDA. In the same announcement, EPA also stated that the only acceptable alternatives to EDB for citrus were cold treatment and fumigation with methyl bromide.

EPA said that it was deferring the establishment of a tolerance for mangoes—the imported commodity most frequently fumigated with EDB. EPA noted that the mango growing and shipping season was just starting and they did not have enough residue data to take final action at that time.

On August 10, 1984, EPA proposed establishment of a 30 ppb interim tolerance for EDB on imported mangoes until September 1, 1985. In making the announcement, EPA noted that all domestic use of EDB on mangoes would still be banned as of September 1, 1984. EPA said it had been informed by Mexico—which accounts for over 80 percent of the market—that its mangoes could meet a 30 ppb standard, but EPA also noted that there was no data to substantiate that assertion.

11. Questions about alternatives to EDB

Carbon tetrachloride has been mentioned as a possible replacement for EDB for grain fumigation and, as noted, methyl bromide was cited as the only pesticidal alternative to EDB for citrus fumigation. Both of these pesticides are also in the RPAR process.

In October 1980, EPA issued a PD-1 on carbon tetrachloride citing its cancer-causing potential as well as adverse chronic liver and kidney effects. The Subcommittee's investigation showed that virtually nothing was done on the RPAR until early 1984, after the EDB suspensions were announced. On March 16, 1984, EPA issued a Data Call-In¹¹ for carbon tetrachloride as part of a project on fumigants and requested among other things, a teratology (malformation) study on two animal species and a reproduction study on one species. Even though such studies are long term, EPA testified that they had scheduled issuance of the PD-2/3 on carbon tetrachloride for the next fiscal year.

On July 2, 1981, EPA issued a Data Call-In on the other alternative to EDB, methyl bromide, which required a cancer study on two species and a reproduction study on one species. However, EPA did not even advise registrants of the results of the call-in until September 7, 1982. One of the studies related to the Data Call-In on

methyl bromide is a biotest of Health's National Toxicology Program. He testified that the final report on the biotest was completed. He also testified that the biotest was being conducted by the Dutch Government which was completed.

D. AC

On March 4, 1984, EPA announced a special review of all pesticides in the RPAR. The action on dicofol was contaminated by dicofol, and that use of dicofol was non-target wildlife, and that use of dicofol was the first RPAR or special review by EPA since April 1972. EPA's ability to deal with dicofol in a timely manner.

In 1972, EPA banned dicofol from the RPAR though dicofol products were not included in the RPAR. EPA's ability to deal with dicofol in a timely manner.

In 1972 when we banned dicofol, which were inadequate, and did not use DDT, which was not through all the

Because almost 300 active ingredients in other cases in which EPA considered "inert" ingredients.

In 1979, EPA initiated a special review of dicofol and shortly thereafter dicofol was present as an ingredient in dicofol products. EPA officials could not initiate a RPAR or regulations require it to be a pesticide may pose an environmental hazard. Testimony of EPA officials against initiation until the entire registration

¹¹ The Data Call-In Program is described in detail on p. 20 of this report.

¹² Hearings, June 7, 1984.
¹³ Testimony of Devra Lee Davis, U.S. House of Representatives, Environment, House Energy and Commerce Committee.
¹⁴ The Registration Standards

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n on the other alterna- l a cancer study on two ies. However, EPA did f the call-in until Sep- to the Data Call-In on

this report.

methyl bromide is a bioassay being conducted by the National Institutes of Health's National Toxicology Program. Dr. Moore testified that the final report on that two-year study is due about 1987. He also testified that there is a rat inhalation study on methyl bromide being conducted in the Netherlands under the aegis of the Dutch Government which is about a year away from being completed.

D. ACTIONS REGARDING DICOFOL

On March 4, 1984, EPA issued notice that it was initiating a special review of all pesticide products containing the active ingredient dicofol. The action was taken because EPA has determined that dicofol was contaminated with DDT and chemically related compounds, and that use of pesticides containing dicofol posed a risk to non-target wildlife, particularly bird populations. While this was the first RPAR or special review action which had been initiated by EPA since April 1981, it again raised serious questions about EPA's ability to deal with potentially dangerous pesticides in a timely manner.

In 1972, EPA banned the use of pesticides containing DDT. Although dicofol products had been registered since 1957, EPA did not include them in the 1972 DDT ban because the DDT and related compounds in dicofol were listed as inert ingredients as opposed to active ingredients. Dr. Edwin Johnson testified:

In 1972 when we canceled DDT, we went through files which were inadequately indexed as far as inert ingredients went, and did not look at dicofol. We looked at active uses of DDT, which were primarily insecticidal uses and not through all these inerts.¹²

Because almost 300 active ingredient pesticides are also included as inert ingredients in other pesticides,¹³ it is likely that there are other cases in which EPA has overlooked dangerous or potentially dangerous pesticides during regulatory action because they were considered "inert" ingredients.

In 1979, EPA initiated a Registration Standard¹⁴ review of dicofol and shortly thereafter someone in EPA discovered that DDT analogs were present as impurities in dicofol products. Although registrants of dicofol products had been submitting confidential statements of formula since 1957, showing DDT as an inert ingredient, EPA officials could not explain why it took EPA reviewers until 1979, 22 years later, to discover the presence of DDT in dicofol. Even after this belated discovery, EPA did not immediately move to initiate an RPAR or special review of the pesticide, though its regulations require it to do so when it determines that a registered pesticide may pose an unreasonable risk to man or the environment. Testimony of EPA officials showed that they consciously decided against initiation of an RPAR or special review of dicofol until the entire registration standard process was completed. EPA

¹² Hearings, June 7, 1984.

¹³ Testimony of Devra Lee Davis, Ph.D., NAS, Before the Subcommittee on Health and the Environment, House Energy and Commerce Committee, May 24, 1984.

¹⁴ The Registration Standards program is described in detail at a later point in this report.

officials defended their waiting for completion of the registration standard before initiating a special review on the grounds that they wanted to determine whether there were any additional RPAR triggers. Consequently, EPA continued to violate its own regulations by not initiating an RPAR action on dicofol until March 1984—more than four years after it finally realized that DDT was present in dicofol.

IV. REREGISTRATION OF OLDER (PRE-1972) PESTICIDES

EPA's Registration Standards program, developed to accomplish the legislatively-mandated reregistration of pesticides products, involves a review of the scientific data base underlying pesticide registrations and an identification of essential, but missing, scientific studies which might not have been required when the product was initially registered. It may also require new testing to ensure the safety of the compound by contemporary scientific standards.

Rather than dealing with individual products, EPA's program involves making regulatory decisions for a whole group of pesticide products containing the same active ingredient. An estimated 600 standards will be developed representing most of the 50,000 pesticide registrations. To establish the sequence for processing the approximate 600 active ingredients through the Registration Standard review, EPA clustered active ingredients that have similar use(s) into 48 groups. The groups are being processed in a sequence resulting from their ranking in an equation based on production, human exposure, and ecological exposure factors.

The published Registration Standard Document explains EPA's regulatory position on the use of the active ingredient in all pesticide products containing that same chemical. The Standard contains an analysis of the data on which the regulatory position is based, describes the rationale for the regulatory position, and states the conditions that must be met to obtain pesticide product registration.

A. SERIOUS LAGS IN PROGRAM ACTIVITY

The Subcommittee found that between 1972 and the end of fiscal year 1983, EPA had issued Registration Standards for only about 64 of the 600 chemicals subject to that requirement. Dr. Moore testified that as of June 7, 1984, EPA had completed 76 registration standards and was then working at a pace of 25 standards per year. However, even if EPA continues working at the rate of 25 standards per year, it would not complete issuing standards for all 600 chemicals until the year 2005.

More importantly, issuance of the standard does not complete reregistration of the pesticides, it merely identifies data gaps. Reregistration is completed only when the registrants (1) comply with all data requirements listed in the standards; (2) submit acceptable new labels; (3) submit new Confidential Statements of Formula; and (4) comply with the data compensation provisions of FIFRA.

By April 1983, EPA had actually reregistered only 70 pesticide products representing four active ingredients. In April 1983, EPA suspended the reregistration of pesticides because the U.S. District Court for the Eastern District of Missouri in the case of *Monsanto*

v. EPA found portions (lease) of FIFRA unenforceable. The Court reversed and remanded the case. The suspension of the additional 360 products was terminated by March 1984. However, 430 or less than one percent of the reregistration requirements

B. POSSIBLE ASSISTANCE

The Subcommittee noted that the registration of pesticides is a task which the Drug Administration would have approved or not they met the requirements of the Amendments Act of 1972. FDA tried to review using its own standards, but the sheer volume of new responsibilities.

Finally, around 1965, the Subcommittee entered into a contract with the National Research Council to study the quantity and quality of the data.

NAS/NRC did this to help colleges and universities to help NAS/NRC committees to get scientific data, FDA was able to bring the pre-1962 new drugs to remove them from the market resulting from the program now being completed. It is a similar system could be an option to the current system.

In early 1984, the NAS/NRC issued a report on the needs and priorities for the fraction of more than 600 and exposure information assessment. In view of the constraints at EPA, Subcommittee 1984, wrote Dr. Frank L. NAS/NRC would be helpful in reviewing and assessing pesticides similar to the 1962 new drugs. Specific Toxicology and Environmental: (1) providing the additional data on pesticides; (2) in which additional data is appropriate short-term toxic

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172) PESTICIDES

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red only 70 pesticide . In April 1983, EPA ause the U.S. District the case of *Monsanto*

v. *EPA* found portions of sections 3 (registration) and 10 (data re- lease) of FIFRA unconstitutional. (In June 1984, the Supreme Court reversed and remanded the District Court's decision in the *Monsanto* case.) The suspension of reregistration actions held up an additional 360 product reregistrations between April 1983 and March 1984. However, even if the latter products had been reregistered by March 1984, EPA would have completed action on only 430 or less than one percent of the 50,000 registrations subject to the reregistration requirement.

B. POSSIBLE ASSISTANCE OF NATIONAL ACADEMY OF SCIENCES

The Subcommittee noted that EPA's situation regarding re-regis- tration of pesticides is analagous to that faced by the Food and Drug Administration when it was required to review all the drugs which it had approved between 1938 and 1962 to determine wheth- er or not they met the tougher standards imposed by the Drug Amendments Act of 1962, and particularly the effectiveness re- quirements. FDA tried in vain for several years to complete such a review using its own staff but was unable to do so because of the sheer volume of new incoming applications and other regulatory responsibilities.

Finally, around 1965, the Commissioner of Food and Drugs en- tered into a contract with the National Academy of Sciences/National Research Council (NAS/NRC) to review and assess the quan- tity and quality of the scientific data to support the pre-1962 new drugs.

NAS/NRC did this by tapping the resources of the nation's col- leges and universities through its boards and committees. Once the NAS/NRC committees had completed their assessment of the scien- tific data, FDA was able to proceed with regulatory proposals to bring the pre-1962 new drugs into conformity with existing law or to remove them from the market. Even so, the regulatory actions resulting from the project have taken over 20 years and are only now being completed. Dr. Moore testified that use of the NAS/NRC or a similar system continued to be considered by EPA as a possi- ble option to the current process.

In early 1984, the NAS's Board on Toxicology and Health Haz- ards issued a report entitled "Toxicity Testing Strategies to Deter- mine Needs and Priorities," which concluded that for only a small fraction of more than 65,000 chemical substances is enough toxicity and exposure information available for a complete health hazard assesment. In view of NAS' interest in the area and manpower con- straints at EPA, Subcommittee Chairman Synar, on August 13, 1984, wrote Dr. Frank Press, President, NAS, to determine whether NAS/NRC would be willing and able to provide assistance to EPA in reviewing and assessing the scientific information on pre-1972 pesticides similar to that it provided to FDA with respect to pre- 1962 new drugs. Specifically, the Chairman asked if the Board on Toxicology and Environmental Health Hazards could assist EPA in: (1) providing the added expertise to review the limited existing data on pesticides; (2) identifying priority classes of ingredients for which additional data should be required; and (3) identifying appro- priate short-term toxicity screening tests that EPA should require

for those 90 percent of the cases where insufficient toxicity data are estimated to exist.

C. DATA CALL-IN PROGRAM

To facilitate the reregistration of older pesticides, EPA instituted a Data Call-In Program, in which it requires existing registrants of active pesticide chemicals to provide the Agency with long-term chronic toxicological studies needed to reassess chemicals during the Registration Standard Process.

The purpose of Data Call-In is to assure that data from needed long-term testing (2-4 years) are available or well underway before the pesticide chemical is reassessed for reregistration. These long-term studies are essential to provide the chronic health effects data needed to determine whether a pesticide performs its intended function without causing unreasonable adverse effects on health or the environment.

EPA requires a chronic feeding study as well as specific studies to determine whether use of the pesticide might cause tumors, birth defects, or reproductive disorders. Under the Data Call-In Program, EPA (1) determines which of four types of chronic test data are required for each chemical; (2) identifies those test categories with no valid data on hand; and (3) ensures that studies are initiated by registrants of the pesticide product to fill those data gaps.

Data Call-In Notices are issued in accordance with Section 3(c)(2)(B) of FIFRA, which authorizes EPA to require the submission of any additional data necessary to maintain an existing registration. Recipients of the notices are given 90 days to inform EPA of how and when they intend to provide the requested data. (Registrants which have end-use products, as opposed to manufacturing-use products, are generally granted exemptions from the data requirements if one of the suppliers of the active ingredients agrees to provide the requested data). If recipients of a Data Call-In Notice fail to respond within the 90-day period, EPA can initiate action to cancel the pesticide registration.

As of September 1983, EPA has issued Data Call-In Notices for only about 165 of the 578 active pesticide ingredients involved in the program.

Dr. Moore testified that EPA had completed 225 Data Call-Ins as of June 7, 1984 and was proceeding with them at the rate of about 75 per year. If EPA continues at a rate of 75 per year, it could not complete the Data Call-Ins before 1989.

V. EMERGENCY EXEMPTIONS

Section 18 of FIFRA provides that EPA may exempt any Federal or State agency from the registration requirements of the act if it determines that emergency conditions exist which require such an exemption. Under EPA regulations, an emergency is deemed to exist when (1) a pest outbreak has or is about to occur and no registered pesticide or alternative method of control is available to eradicate or control the pest; (2) significant economic or health problems will occur without the use of the unregistered pesticide; and (3) the time available from discovery or prediction of the pest

outbreak is insufficient for the use of the registered pesticide.

A. TYPES OF EXEMPTIONS

EPA provides for three types of exemptions: (1) emergency exemptions, (2) public health, and (3) crisis exemptions. Emergency exemptions are valid only for those circumstances where the use of the pesticide is necessary to prevent the spread of a pest. Such exemptions are granted for a period of time longer than one year.

Any Federal or State agency may apply for an exemption in a situation where the use of a pesticide is necessary to prevent the spread of a pest. (1) that there is no other method of control available to eradicate the pest; (2) that there was no time to register the pesticide; and (3) that the crisis exemption is in effect. EPA of the determination must file a detailed report with the Administrator within 15 days of the date of the exemption. The latter report must specify the nature of the pesticide, the nature of the pest, the nature of the emergency, and the nature of the public health exemption. The latter report must also specify the nature of the public health exemption and the nature of the crisis exemption.

B. WHOLESALE GRANTS OF EXEMPTIONS TO THE LEGITIMATE USER

Between 1978 and 1983, the number of emergency exemptions increased from 165 per year to 429 per year. EPA issued about 429 emergency exemptions in 1983. All 49 requests for emergency exemptions were granted by EPA. While specific exemptions, Federal and State agencies did not require prior approval from the State of California.

EPA officials attribute the increase in emergency exemptions to applicants' unfamiliarity with the requirements of the act. Many had no economic

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outbreak is insufficient for a pesticide to be registered for the particular use.

A. TYPES OF EXEMPTIONS AND USER REQUIREMENTS

EPA provides for 3 types of exemptions: specific, quarantine-public health, and crisis. A specific exemption may be issued in a situation involving the outbreak of a pest in the U.S. Such exemptions are valid only for the specific situation involved, but in no circumstances may be longer than one year. Specific exemptions prescribe use restrictions, including the quantity of pesticide, conditions under which the pesticide may be applied, persons who may apply the pesticide and the type of monitoring which should be conducted. A quarantine-public health exemption may be issued to cover Federal or State programs concerned with preventing the introduction or spread of a foreign pest into or throughout the U.S. Such exemptions are valid only for the time specified but in no instance longer than one year.

Any Federal or State agency is authorized to initiate a crisis exemption in a situation involving the unpredictable outbreak of pests in the U.S. when the responsible agency official determines (1) that there is no readily available pesticide registered for the particular use to eradicate or control the pest; and (2) that the time element with respect to the application of the pesticide is so critical that there was no time to request a specific exemption. After a crisis exemption is initiated, the responsible official must notify EPA of the determination and ten days after using the pesticide must file a detailed report on the application. If the treatment pursuant to the crisis exemption is expected to continue for more than 15 days the latter report must be accompanied by an application for a specific exemption. Applications for specific and quarantine-public health exemptions must contain detailed descriptions of the nature of the pesticidal problem and the proposed treatment. Agencies which receive specific exemptions must send a detailed report to EPA on the use of the pesticide. Agencies which receive quarantine-public health exemption must retain detailed records of the application for EPA's inspection.

B. WHOLESALE GRANTING OF EXEMPTIONS RAISES QUESTIONS ABOUT THE LEGITIMACY OF "EMERGENCY" SITUATIONS

Between 1978 and 1982 the number of emergency exemptions increased from 165 per year to 727 per year—a four-fold increase and a 45 percent average annual growth rate. During fiscal year 1983, EPA issued about 429 specific and quarantine-public health exemptions. All 49 requests for quarantine exemptions by APHIS were granted by EPA. While states were granted about 379 requests for specific exemptions, EPA denied only about 50 such requests. Federal and State agencies declared about 116 crisis exemptions, which did not require prior EPA approval, during fiscal year 1983. The State of California alone declared 32 crisis exemptions.

EPA officials attributed the growth of exemptions to potential applicants' unfamiliarity with the program in the early years and with situations involving minor use crops where the pesticide company had no economic reason to seek regular registration. They

said that an audit of the program had shown that most of the reasons for the growth in exemptions were valid; however, there were circumstances where: (1) there was no real emergency; (2) the exemption was a circumvention of the regular registration requirements; and (3) a more aggressive program for approval of minor pesticide uses could have eliminated the need for some such exemptions.

The Subcommittee's investigation confirmed these findings and found other problems in EPA's emergency exemption program as shown by the following examples.

1. *Larvadex*

Of all the pesticides involved in fiscal year 1983 exemptions, Larvadex, which is a trade name for cyromazine, had the most widespread use. About 28 States obtained exemptions for the use of Larvadex to control flies in poultry houses. Larvadex is added to the feed, passes through the bird, and prevents flies from hatching in the bird's manure. An application for registration of Larvadex has been pending with EPA for two to three years and, beginning in 1981, States began requesting emergency exemptions for its use, including States which experienced an outbreak of contagious avian flu.

a. *Questionable state of emergency*

There are 7 or 8 non-feed alternatives to Larvadex and the one apparent major advantage of using it in lieu of non-feed alternatives is its convenience. The State of California refused to register Larvadex in 1983. In an internal California Department of Food and Agriculture memorandum, dated February 18, 1983, to George Reese, Chief, Pesticide Registration Unit, Dr. Keith T. Maddy, Chief/Staff Toxicologist Worker Health and Safety Unit, questioned both the use of a feed-through product because it would result in unnecessary residues, and whether, in fact, an emergency situation existed because of available alternatives. Dr. Maddy stated:

The alleged crisis in California appears to be that some County Health Departments have asked some poultry house operators to better control their flies since their buildings are close to human habitations. These recommendations are appropriate. Currently registered products which can be effective with proper use are available in California for those poultrymen who do not have adequate manure flush-out systems. Clearly, if the representatives of the public elected to Congress allow us to permit emergency pesticide registration without complete data availability to meet local crises, we certainly should be conscientious not to abuse the delegated authority (or we may lose it).

On the second issue, that of full section 3 registration, I have serious reservations about this method and approach to fly control. The administration of a pesticide chemical to chickens for the purpose of controlling flies attracted to their manure hardly seems justified when production (the

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and the meat are
an added chemical

Likewise, EPA review indicated that it appeared an emergency. In a letter 1983, Douglas the Benefits and Use

Fly infestation
not a new problem

Larvadex in convenience and avian flies. Of the pesticides, Larvadex is the easiest process of mixing further disruption. Alternatives usually require tend to disturb required to act

b. *Cancer clause*

In June 1983, the Ecology Program issued a letter¹⁵ of Larvadex, to control fly rats. As a result, the 28 emergency exemptions in poultry houses. Des Moines initiated a campaign brand name for cyromazine. The State of Pennsylvania refused Larvadex to control avian flu virus—the Dr. Moore stated that have taken the crisis seriously that the crisis that EPA would have agency and request 1983, EPA granted Larvadex in poultry houses.

In granting the exemptions that the assessment discussions with FDA the benefits to be weighed risks, which appear termination was made and EPA scientists

¹⁵ Hearings, June 7, 1984.

¹⁶ Hearings, June 7, 1984.

¹⁷ A metabolite is a breakdown

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well being of the chickens or their eggs) is not benefited
and the meat and eggs to be eaten by people will now have
an added chemical residue burden.¹⁵

Likewise, EPA reviewers in discussing use of Larvadex exemptions
indicated that it appeared to be more a matter of convenience than
an emergency. In a Brief Benefits Review for cyromazine dated Oc-
tober 1983, Douglas W. S. Sutherland and William D. Schutte of
the Benefits and Use Division of the OPP stated:

Fly infestations in and around egg producing facilities is
not a new problem.

* * * * *

Larvadex is valued by egg producers, because of its con-
venience and apparent effectiveness to date at controlling
flies. Of the pesticides available for controlling flies, Larva-
dex is the easiest for the egg producer to use. A one-step
process of mixing the material with the feed allows for no
further disruptions or inconvenience to the producer's op-
eration. Alternative pesticides used as spray treatments
usually require covering water and feed containers and
tend to disturb the birds somewhat, plus involve the time
required to actually spray the facilities.¹⁶

*b. Cancer causing potential and applicability of Delaney
clause*

In June 1983, the National Institutes of Health's National Toxi-
cology Program issued a report on its study of Melamine, a metabo-
lite¹⁷ of Larvadex, which showed that it caused cancer in labora-
tory rats. As a result, on August 19, 1983, EPA temporarily revoked
the 28 emergency exemptions for use of Larvadex to control flies in
poultry houses. Despite the revocation, six days later the State of
Florida initiated a crisis exemption for the use of Trigard (another
brand name for cyromazine) on celery and lettuce. In late 1983, the
State of Pennsylvania initiated a crisis exemption for the use of
Larvadex to control flies in poultry houses to prevent spread of
avian flu virus—the specific use that had previously been revoked.
Dr. Moore stated that he would have preferred that Florida not
have taken the crisis exemption and EPA quickly told Florida offi-
cials that the crisis exemption was not to be taken. Dr. Moore said
that EPA would have preferred that Pennsylvania consult with the
agency and request a specific exemption. However, on December 9,
1983, EPA granted Pennsylvania a specific exemption to use Larva-
dex in poultry houses.

In granting the specific exemption to Pennsylvania, EPA stated
that the assessment of the potential risks for Melamine, including
discussions with FDA, had progressed far enough to determine that
the benefits to be derived from this use outweighed the potential
risks, which appeared to be minimal. Dr. Moore stated that this de-
termination was made as a result of the mutual conclusion of FDA
and EPA scientists that use of Larvadex was unlikely to cause a

¹⁵ Hearings, June 7, 1984.

¹⁶ Hearings, June 7, 1984.

¹⁷ A metabolite is a breakdown product of a chemical.

very high risk and discussion with the State of Pennsylvania and APHIS which indicated that the avian flu situation was "extremely dire."

On April 27, 1984, EPA, proposed tolerances for cyromazine in eggs and poultry as raw agricultural commodities and also proposed a feed additive regulation to permit residues in processed poultry. The Food, Drug and Cosmetic Act generally prohibits the establishment of food additive tolerances for pesticides which have been shown to induce cancer in animals. The so-called Diethylstilbestrol or DES proviso allows the use of a cancer-causing substance as an ingredient in animal feed, but only if no residue will be found in the edible portion of the animal or any food yielded by that living animal. In citing the DES proviso as the basis for recommending a feed additive regulation, EPA adopted an interpretation of FDA's which provided that cancer causing food additives could be allowed if the cancer risk was less than 1 in a million. Apparently, this was the first time that EPA had proposed this approach as a basis for approval of a cancer-causing pesticide as a food additive.

However, on June 29, 1984, EPA announced that it was deferring final decisions to conditionally register Larvadex, to set tolerances for maximum residues of it in eggs, poultry meat and poultry meat byproducts, and to establish feed additive regulations for use of the pesticide in poultry feed, pending the receipt of additional test data from the company. EPA also said that until the additional data are received it will not issue any additional emergency exemptions for use of Larvadex or other cyromazine-containing products and would terminate outstanding exemptions.

2. Mesurol

Another pesticide which was involved in emergency exemptions in numerous States was Mesurol (methiocarb). In fiscal year 1983 about 30 specific exemptions in 19 States involved use of Mesurol. Most of the exemptions (18) were to prevent birds from eating grapes; other uses were to control snails and slugs in a variety of situations. The number of States which were granted specific exemptions for mesurol to prevent birds from eating grapes increased from four in 1979 to 13 in 1982 and as of July 1983 two requests had been granted and 15 applications were pending. The following exchange, between Subcommittee Chairman Synar and Dr. Edwin Johnson, occurred after Chairman Synar asked why it was considered an emergency situation because the problem of birds eating grapes was predictable and recurring. The exchange illustrated problems in the manner in which EPA determines that an emergency exists.

Dr. JOHNSON. Yes, I am a little bit fuzzy on the exact reasons, but there was a holdup in the registration. It was either characterization of metabolites or an analytical method for enforcement. I am not sure exactly what the reason was, but we were unable to register Mesurol under section 3 although it had been in for consideration for some time, and—

Mr. SYNAR. Well, why was that an emergency situation?

Dr. JOHNSON [alternatives that w grapes, and ther tion was in orde our other alterna tered although th it.

Mr. SYNAR. No alternatives, quote effective," or "eff

Dr. JOHNSON. V pling with right ing section 18 ova more effective all

Mr. SYNAR. We tive;" right?

Dr. JOHNSON. review of the pr ourselves when that was, indeed, cy exemption. Is producer a mech section 18, or sh section 3 registra an emergency, o after it has gone much more caref was a borderlin emergency.¹⁸

The Subcommittee questionable involve requests for exemptions for specific exemption were remarkably sin the nature of the err name of the State ar to account for this si either the States got or they were assisted sale of the product.

An OPP audit of needs programs datec volve ment:

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¹⁸ Hearings, June 7, 1984.

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Dr. JOHNSON [continuing]. And there were no other alternatives that were as effective in controlling problems in grapes, and therefore we felt that an emergency exemption was in order because it would solve the problem of our other alternatives, and the product could not be registered although there were attempts being made to register it.

Mr. SYNAR. Now, you know, you said there were no alternatives, quote, "as effective." Did they have to be "as effective," or "effective?"

Dr. JOHNSON. Well, that is one of the issues we are grappling with right now, Mr. Chairman, because in interpreting section 18 over the years, improved economic return or more effective alternatives—

Mr. SYNAR. Well, there will always be only one "as effective;" right?

Dr. JOHNSON. Well, that issue was considered in our review of the program. One of the things that we asked ourselves when we reviewed the program was, whether that was, indeed, an adequate justification for an emergency exemption. Is increased return or increased yield to the producer a mechanism that should be generated through section 18, or should that be generated through a routine section 3 registration? Is a better mousetrap to be used in an emergency, or is a better mousetrap to be used only after it has gone through the full hurdles? We are looking much more carefully at that kind of a justification now. It was a borderline call, frankly, on what constitutes an emergency.¹⁸

The Subcommittee investigation also showed that there was questionable involvement by pesticide producers in some state requests for exemptions. The applications from three different States for specific exemptions to use Mesurol on grapes in fiscal year 1983 were remarkably similar. In fact the first paragraphs describing the nature of the emergency were almost identical except for the name of the State and the number of acres involved. When asked to account for this similarity, Dr. Moore could only speculate that either the States got together and agreed to share a common draft or they were assisted by someone who had a vested interest in the sale of the product.

An OPP audit of the emergency exemption and special local needs programs dated March 1983 also noted pesticide company involvement:

... In some cases, OPP has observed that the involved company provides the information needed to support the state's request for an emergency exemption (and occasionally writes the state's request) including addressing registered alternatives, agricultural economics, and details of the pest problem encountered. Moreover, there have been some cases where more than one state has submitted a virtually identical request, the only differences being in the

¹⁸ Hearings, June 7, 1984.

number of acres to be treated and the number of pounds of pesticide to be used (occasionally, these numbers were added in different type faces). Media articles as well as discussions with state officials indicate that some companies have promoted the use of their products through the section 18 program.¹⁹

The Subcommittee also noted that some States apparently don't even bother to submit detailed applications justifying emergency exemptions. On June 24, 1983, one State sent a short letter to EPA²⁰ requesting an emergency exemption to use Mesurool on grapes. The letter noted that the State had a specific exemption for this use from July 15, 1982 to November 30, 1982, and stated:

... Since the Section 18 exemption has expired, we offer this request in an effort to have use of this product for an additional year and request that information submitted for the original Section 18 be considered sufficient to support this renewed request.

EPA granted the State's request for an exemption on August 8, 1983.

3. Metalaxyl

Another chemical which was involved in numerous specific exemptions was the fungicide Metalaxyl. In fiscal year 1983 about 36 specific exemptions or amendments thereto in 14 States involved Metalaxyl. The exemptions were granted for the use of Metalaxyl to control downy mildew and other diseases on berries, seeds, lettuce, cauliflower, and other garden products.

As in the case of Larvadex, EPA granted the exemptions even though there were unanswered questions about Metalaxyl's cancer causing potential. In a memorandum dated June 10, 1983 to Dr. Edwin Johnson, regarding the applications for use of Metalaxyl on hops in three States, Mr. Douglas D. Campt, Director, Registration Division, noted that:

Toxicology Branch indicates that additional pivotal metalaxyl oncogenicity studies have recently been received and are under review. However, due to other high priority projects a review of these data and final conclusions with respect to metalaxyl's oncogenic potential will not be made in time for section 18 deadlines.²¹

Despite the incomplete data, EPA granted the exemptions that same day. Dr. Johnson testified that the exemptions were granted because based on the available data EPA had no reason to suspect that Metalaxyl was a potent carcinogen and thus the risks if any were considered low. In response to a question during the June 7, 1984 hearing as to whether use of Metalaxyl on hops violated the Delaney Clause, Dr. Johnson replied:

Dr. JOHNSON. No, sir, I do not believe it does. There is no positive evidence that metalaxyl, in fact, causes oncogeni-

city. There are some data that were submitted that were submitted to issue any more data, but it has been determined.

Mr. SYNAR. Yes.

Dr. JOHNSON. From some emergency exemptions, but it has been determined that our determination is out, probably have determinations, and not determinations for the emergency studies couple of teratogenicity studies. It is on hold, it is on hold.

Also, in the previous hearing, Mr. Campt.

The Pesticide Branch consulted. Due to raw agricultural commodities chronic febrile mutagenicity a ration of this emergency exemption.

C. UNTIMELY APPROVAL

States are required to retain detailed records of pesticides under emergency exemption. Subcommittee review in 1983 revealed that reports. Subcommittee around to reviewing reports, Dr. Moore stated as effectively as to be addressed. Headquarters had sufficient the use of Section 18 attention to this area.

D. REVISIONS TO

EPA said that the exemption procedure: registration process EPA. Washington, D.C., comments on EPA's hearings on those hearings, committee and an

¹⁹ Hearings, June 7, 1984.

²⁰ Letter available for review in Subcommittee offices.

²¹ Hearings, June 7, 1984.

²² Hearings, June 7, 1984.

²³ Hearings, June 7, 1984.

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city. There are, indeed, some questions about the studies that were submitted which have caused us to refuse to issue any more section 18's or to issue the requested tolerances, but it has been—

Mr. SYNAR. What is the present status?

Dr. JOHNSON. The chemical is unregistered, and aside from some emergency exemptions which were issued prior to our determination not to issue any more, they are phasing out, probably are phasing out in June, I believe. We have determined not to issue any more emergency exemptions, and not to issue any further tolerances or registrations for the material until we have more conclusive oncogenicity studies on this chemical. There also needs to be a couple of teratology studies submitted on the chemical, so it is on hold, in other words, until there is better data.²²

Also, in the previously cited June 10, 1983 memorandum to Dr. Johnson, Mr. Camppt pointed out:

The Pesticide Registration Standard for metalaxyl was consulted. Due to the lack of a registered use pattern on raw agricultural commodities, the standard does not discuss chronic feeding studies, oncogenicity, reproduction, or mutagenicity and, therefore, was of no utility in the preparation of this exemption . . .

C. UNTIMELY AND INEFFECTIVE MONITORING OF USAGE UNDER EXEMPTIONS

States are required to submit detailed reports to EPA on the use of pesticides under specific exemptions and Federal agencies are to retain detailed records of the treatment for EPA's inspection. The Subcommittee review of the emergency exemptions for fiscal year 1983 revealed that almost none of the files contained the required reports. Subcommittee staff was told that EPA was just getting around to reviewing these reports. In testimony before the Subcommittee, Dr. Moore stated that this was an area which was not operating as effectively or efficiently as it should be and clearly needed to be addressed. He also testified that neither EPA regions or headquarters had sufficient resources to pursue aggressive follow-up of the use of Section 18 exemptions and that EPA was paying more attention to this area in an effort to improve their ability.²³

D. REVISIONS TO EMERGENCY EXEMPTION REGULATIONS TO BE PROPOSED IN 1985

EPA said that because of agency and public concerns that the exemption procedures could be misused to circumvent the full registration process EPA held public hearings during January 1984 in Washington, D.C., Kansas City, and San Francisco to obtain comments on EPA's handling of emergency exemption requests. Based on those hearings, as well as a 1979 report from a Congressional committee and an internal audit of the exemption program, EPA

²² Hearings, June 7, 1984.

²³ Hearings, June 7, 1984.

stated that it will propose revision of its emergency exemption regulations early in 1985.

Dr. Moore also stated that new policy directives were now in place regarding emergency exemption requests which would:

- (1) Provide for publication in the Federal Register and public comments on receipt of all applications for emergency exemptions involving a new chemical (one not yet registered); and
- (2) Prohibit granting emergency exemption requests involving unregistered chemicals unless there is a compelling public interest reason. If such requests are granted, a notice explaining EPA's rationale will be published in the Federal Register.

VI. QUALITY OF DATA SUPPORTING PESTICIDE REGISTRATIONS AND EPA'S REVIEW AND INSPECTION PROCEDURES

The 1972 amendments to FIFRA mandated more stringent safety standards for new pesticides, which required registrants to submit more comprehensive studies in support of product registrations.

A. FALSIFIED STUDIES SUBMITTED BY INDUSTRIAL BIOTEST LABORATORIES

In 1976, Industrial Biotest Laboratories (IBT) was one of the largest independent laboratories used by industry to perform animal studies in support of pesticide applications.

During that year a routine FDA inspection of IBT uncovered serious deficiencies and improprieties in the manner in which animal toxicology studies were conducted by IBT, as well as substantial discrepancies between the raw data and the final reports. The IBT case was referred to the Justice Department and in October 1983 three former IBT officials were convicted in Federal Court of fabricating key product safety tests used to gain government marketing approval for two popular pesticides and two commonly used drugs.

Since IBT was one of the largest independent laboratories used by the pesticide industry both in this country and in Canada, EPA and the Health Protection Branch (HPB) of the Canadian Department of Health and Welfare in 1977 requested that registrants audit pivotal studies performed in support of pesticide tolerances. Pivotal studies were those which were submitted to assess potential human health effects, and included studies such as chronic feeding, carcinogenicity, multigeneration reproduction, teratogenicity, and subacute feeding. Registrants were required to submit a validation report for each study, stating the results of their audit as well as a microfiche copy of all raw data relating to that study.

In July 1978, EPA and HPB entered into a cooperative agreement to share the workload in cases where registrants had submitted identical reports to support registrations or tolerances in both countries. EPA and HPB reviewed the registrant's validations and the supporting raw data for all pivotal studies prior to a final determination on the validity of each specific study.

The EPA and HPB validation reviews took approximately 5 years and showed that only about 10 percent of the over 2000 IBT studies which had been submitted in support of pesticide registrations were valid. Some of the practices which resulted in invalid studies were:

Filthy conditions caused countless deaths to the sponsor.
Fabricated data.
A scheme to circumvent.
Routine falsification.

B. PROBLEMS

In May 1982, EPA began to reexamine previous credit that during the studies which had been were, in fact, invalid. The joint working group on OPP, discussed the number of study valuations. Canadian difference states, in part:

All 48 studies originally considered in the shop, HED [Hazardous Evaluation Division] reviewed 19 of them and found them invalid as follows:

Summary statistics. Keaney of EPA on 10 studies reviewed by EPA, on 10 valid, but of the 479 percent) were deemed that he did not know of the studies valid. The exact extent of the studies in Canada and what EPA.

Dr. Johnson said that the studies which previous government they were whether they were acceptable or that has been compared to the normal range.

In a memorandum dated March 17, 1983, the Health Protection Branch/HED stated, "we are committed to the IBT studies validate to Douglas D. Campbell, Ferial S. Bishop, Chief, that Larry Chitlik would not validate a future."²⁷ The memorandum

²⁴ Hearings, June 7, 1984.

²⁵ Hearings, June 7, 1984.

²⁶ Hearings, June 7, 1984.

²⁷ Hearings, June 7, 1984.

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Filthy conditions in laboratory animals' feeding rooms
caused countless deaths of rats and mice that were not report-
ed to the sponsors of the studies or to the government;

Fabricated data tables and forged supervisory approvals;
A scheme to cover up high animal mortality rates; and
Routine falsification of data and alteration of test reports.

B. PROBLEMS WITH VALIDATIONS PERFORMED BY CANADA

In May 1982, EPA and HPB Canada held a joint working meet-
ing to reexamine previously reviewed IBT studies. It is to EPA's
credit that during the meeting it was determined that many of the
studies which had been reviewed by Canada and deemed valid
were, in fact, invalid. A memorandum which was prepared after
the joint working meeting, to Dr. Johnson from Bill Dickinson of
OPP, discussed IBT validation and contained an analysis of the
number of study validations for which there may have been a U.S./
Canadian difference of opinion. In the memorandum Mr. Dickinson
states, in part:

All 48 studies were validated by HPB, Canada and were
originally considered valid but, as a result of the work-
shop, HED [Hazard Evaluation Division] staff now consid-
ers 19 of them as invalid. The remaining 29 have not been
reviewed by HED but it is likely that they would consider
them invalid as well.²⁴

Summary statistics on IBT studies apparently authored by Kevin
Keaney of EPA on February 9, 1983 showed that of 642 studies re-
viewed by EPA, only 81 (or 13 percent) were determined to be
valid, but of the 479 studies reviewed by Canada, 133 (or almost 28
percent) were deemed valid. During hearings, Dr. Johnson said
that he did not know why Canada found more than twice as many
of the studies valid as did EPA, and his testimony was vague on
the exact extent of the problem with IBT studies validated by
Canada and what EPA did to correct the situation.

Dr. Johnson said that EPA decided that when they evaluated the
studies which previously were regarded as valid by the Canadian
government they would make a further determination as to wheth-
er they were acceptable. Dr. Johnson stated, "I am not sure wheth-
er that has been completed or not yet. It was to be taken up as
part of the normal review of these chemicals."²⁵

In a memorandum to John W. Melone, Director, HED, dated
March 17, 1983, Laurence D. Chitlik, Section Head, Toxicology
Branch/HED stated, "Also, as per our meetings with Ed Johnson,
we are committed to completing evaluations of approximately 50
IBT studies validated by Canada."²⁶ However, in a memorandum
to Douglas D. Campt, Registration Division, dated March 24, 1983,
Ferial S. Bishop, Chief, Process Coordination Branch, OPP noted
that Larry Chitlik informed her that John Melone decided he
would not validate additional studies that may be identified in the
future.²⁷ The memorandum also states that HED has decided that

²⁴ Hearings, June 7, 1984.

²⁵ Hearings, June 7, 1984.

²⁶ Hearings, June 7, 1984.

²⁷ Hearings, June 7, 1984.

they will not evaluate any additional IBT toxicology studies validated by Canada. In response to a question as to why HED stopped working on additional IBT studies when there was apparently so much work still to be done, Dr. Johnson stated:

... We have determined during the review of all the IBT studies that most of the studies were invalid. It seemed that every time we turned around, we uncovered another IBT study that somebody didn't know about, and wasn't in the original list, and we made a determination as reflected in the first decision that we not waste our resources validating or attempting to validate any more studies, but just to call them invalid, period, and require replacement, if we stumbled across any more studies that we hadn't previously identified.

With respect to the second decision, I do not know the exact reason for that decision. We have made a specific decision to evaluate these studies, and I think this memorandum is more related to a question of timing. Do we sit down and evaluate those studies as a block, or do we evaluate them when we review the chemical for some other purpose? And I believe that that is the intent of the decision that is reflected here. We will not make it a special project to evaluate those studies independently, but rather when we review the chemicals and those studies are germane for some other reason, then we will evaluate them at that time.²⁸

Chairman Synar later asked Dr. Johnson how many studies remain to be validated or evaluated by EPA; Dr. Johnson replied:

I don't have a specific number. There are the 10 obviously here that were determined not to be reviewed and just considered invalid, and then there would be the numbers of studies from the Canadian task force that would be looked at during the course of the registration standards process, in the evaluation program.²⁹

C. QUESTIONABLE REDUCTIONS IN THE NUMBER OF IBT STUDIES TO BE REPLACED

In an August 13, 1982 memorandum to John Melone on the IBT audit program, William C. Dickinson, Acting Director, Special Pesticide Review Division, noted that "with a universe of over 2,000 studies, we would not be at all surprised that there are some errors in our lists of studies."³⁰ In early 1983, EPA developed an initial matrix of IBT studies which identified only 1,205 studies involving 44 companies and 212 chemicals. Dr. Johnson was unable to give a specific reason for the sizable reduction in the number; however, he stated there were a large variety of studies, such as acute toxicity, fish and wildlife, and environmental studies, which were not human health studies or relevant to major determinations on pesticides. Dr. Johnson conceded that the acute studies were important

and required for re of urgency as long-t EPA would make si ing purposes during

In July 1983, EPA IBT studies involve evaluations and th only 801 studies. M only 724 studies w 581 of the 1,205 stu being relevant to th

D. UNTIMELY A UNNEC

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E. EVENTUAL REGI TIMEL

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²⁸ Hearings, June 7, 1984.

²⁹ Hearings, June 7, 1984.

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and required for registration, but did not involve the same degree of urgency as long-term toxicology data. Dr. Johnson further stated EPA would make sure it had an adequate acute data base for labeling purposes during the registration process.

In July 1983, EPA finally published its first formal matrix of the IBT studies involved, including the results of the validation and evaluations and the status of replacement studies, which showed only 801 studies. Moreover, Dr. Johnson testified that there were only 724 studies which were of primary concern to EPA and that 581 of the 1,205 studies in the original matrix were deleted as not being relevant to the kinds of health effects of interest to EPA.

D. UNTIMELY ACTION BY EPA IN THE IBT SITUATION CAUSED UNNECESSARY CONFUSION AND UNCERTAINTY

It took EPA seven years—from 1976 when an FDA lab audit revealed problems at IBT, until July 1983—to formally publish information on the scope of the problem involved. While the chemicals involved had generally been known all this time, neither pesticide manufacturers, registrants, users, nor the public knew whether the pesticides were supported by adequate safety data. The delay was especially crucial in cases where replacement studies would be needed because many of the pivotal studies are long-term and very expensive. Dr. Johnson testified that given the level of resources available it wasn't until 1983 that EPA could make some kind of comprehensive report rather than merely a progress report.

E. EVENTUAL REGULATORY ACTION FELL FAR SHORT OF OBTAINING TIMELY REPLACEMENT OF INVALID STUDIES

On February 9, 1982, the Deputy Director of the Special Pesticide Review Division informed the Director, HED, that he was ready to send 3(c)(2)(B) [90 day response] letters to registrants of 43 chemicals involved in the IBT Case. However, such letters were sent to registrants of only 8 chemicals. EPA could not even find a listing of the 43 chemicals referred to in the February 9, 1982 memorandum. EPA submitted information for the June 7, 1984 hearing record which stated that it decided not to launch a Data Call-In for IBT replacement studies in 1982, but to channel its resources into preparing a matrix on the status of all IBT studies. EPA said that by July 1983, it had identified 34 pesticides as candidates for 90-day response letters; however, it later determined that 26 of the 34 pesticides did not require such letters. EPA provided the following information as to why the registrants of the 26 chemicals were not sent the 90-day response letters.

Reason letter not sent

	Number
Not registered in the United States	7
Study not needed to support registration	7
Data call-in issued or to be issued in fiscal year 1983	7
Registration cancelled	2
Replacement studies already requested	2
Deferred to registration standard	1

The following table shows the eight pesticides which were sent 90-day response letters, the number of studies involved, and the number of registrants which were issued formal notices.

Pesticide	Number of studies	Number of registrants
Benzadox.....	3	1
Chlorobromuron.....	4	1
Glyphosine.....	11	1
Irganson.....	11	21
Methazole.....	8	2
PPG.....	2	1
Randox.....	6	4
Santophen.....	9	202

1. EPA action regarding Santophen

On July 28, 1983, EPA sent a 90-day response letter to the 202 registrants of products containing Santophen, informing them that 9 studies performed by IBT were invalid and had to be replaced. (Santophen is used in germicidal products such as hospital disinfectants, toilet bowl cleaners, and detergents.) EPA received the following responses from the registrants.

Response	Number
Request for formulator exemption.....	120
Voluntary cancellation.....	36
Agree to provide replacement studies.....	2
No answer.....	44

EPA said that some companies had changed names or moved and it took considerable time and effort to locate and make contact with the 44 registrants who did not respond to the 90-day response letter. EPA said it now had the best possible list of addresses and would mail suspension notices at the end of August 1984.

On September 19, 1983, Mr. A. E. Castillo, Product Manager, Disinfectants Branch, Registration Division, wrote Monsanto Agricultural Products, that based on meetings between EPA and the company, EPA had decided that three of nine studies cited in the 90-day response letter had to be replaced. On October 28, 1983, Monsanto and Mobay Chemical Corporation informed EPA that they had jointly agreed to develop the three studies required by EPA. In fact, Monsanto said they had already submitted one of the three studies—a two-segment rabbit teratology study—on September 30, 1983 and that Mobay would submit the remaining two studies—a 21-day subchronic rabbit study and a teratology rat study. On November 2, 1983, Mr. Castillo wrote Mobay and said that in light of the unusual circumstances and unduly long time it took to reach a decision for the commitment to be made, the deadline for submitting the two outstanding studies would be renegotiated. As a result of the negotiations, Mobay agreed to submit the results of the tests by December 1984.³¹

³¹ Hearings, June 7, 1984.

2. Deferral of replacement or registration studies

EPA's March 29, 1983 letter, of which 183 were needed and entered in the U.S. Of had been accepted progress at the completion of the needed registration standards which will not er Dr. Johnson testified present a problem other laboratories need for replacing a using other companies.

Mr. SYNAR. T staff has said s question of fair play off other p going to be required. What do you other studies.

Dr. JOHNSON. 1978 amendment the basis of all who submitted studies on an a safety conclusion nomic inequity compensation or That was change being reviewed l

As previously noted. However, the mitted to EPA between the public, or allows to's consent, Monsanto U.S. Court of Claims

F. STEPS NEED TO BE TAKEN

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³² Hearings, June 7, 1984.

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	Number of studies	Number of registrants
.....	3	1
.....	4	1
.....	11	1
.....	11	21
.....	8	2
.....	2	1
.....	6	4
.....	9	202

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2. Deferral of replacement studies for other chemicals to data call-in or registration standards programs

EPA's March 29, 1984 matrix of IBT studies shows only 747 studies, of which 183 were for chemicals for which no replacement studies were needed and 172 were for chemicals which were not registered in the U.S. Of the remaining 392 studies, 243 or 62 percent, had been accepted by EPA, were under review at EPA, or were in progress at the company. However, the remaining 149 (or 38 percent) of the needed replacement studies had been deferred to the registration standards or data call-in programs, including 38 studies which will not enter those programs until after fiscal year 1985. Dr. Johnson testified that the language used in the matrix may present a problem because in some cases EPA had studies from other laboratories submitted by other companies which negated the need for replacing an invalid IBT study. Regarding the fairness of using other company's studies, the following exchange took place:

Mr. SYNAR. There may be a question here, and I think staff has said something that is important. There is the question of fairness as to whether or not companies can play off other people's studies or whether or not they are going to be required to have their own studies.

What do you think about that? You are pointing to other studies.

Dr. JOHNSON. Well, the agency took a position in the 1978 amendments to FIFRA that we should regulate on the basis of all information available to us regardless of who submitted those studies. That means taking all the studies on an active ingredient and reaching health and safety conclusions based on those. If there were any economic inequity involved in this, that would be handled by compensation or a payment for the data.

That was challenged in the courts, and it is currently being reviewed by the Supreme Court.³²

As previously noted, the Supreme Court upheld EPA's interpretation. However, the Court also ruled that with regard to data submitted to EPA between 1972 and 1978, if EPA now discloses it to the public, or allows other companies to rely on it without Monsanto's consent, Monsanto may be entitled to recover damages in the U.S. Court of Claims.

F. STEPS NEED TO BE TAKEN TO PREVENT A RECURRENCE OF THE IBT SITUATION

There are approximately 400 laboratories which perform tests on pesticides and other chemicals which are submitted to EPA, FDA and other regulatory agencies in connection with regulatory actions. EPA and FDA now have a joint program in which they attempt to visit about 40 laboratories each year to determine whether they follow good laboratory practices, and, in a few cases, to audit specific studies to see whether the conclusions in the studies are supported by the raw data.

³² Hearings, June 7, 1984.

To validate IBT studies, reviewers had to go back to the raw data that is normally not submitted in connection with the reports of studies submitted as part of the pesticide registration application procedure. In order to prevent a recurrence of the IBT situation in the future, Dr. Moore was asked whether it might be a good idea for EPA to require that the raw data be submitted along with the studies; he replied:

Congressman, whether or not it should be submitted, I am not sure. I don't foreclose on that possibility, particularly if one could get them into microfilm or something like that.

But clearly what needs to be done is some systematic effective process whereby some subset of data is audited and indeed if the audit shows that the data is valid or has been transposed validly, then I think move on. To the degree that one doesn't have such comfort that the validation effort proved that everything was fine, then one has to go through the whole data set or reject the data set until such time as it is re-submitted to appropriate form.³³

VII. SUMMARY OF FINDINGS

A. REBUTTABLE PRESUMPTION AGAINST REGISTRATION (RPAR)

1. The Committee found that the RPAR process is not achieving its intended function of providing an expedited decision by EPA on whether to remove a registered pesticide from the market, or to restrict its use, whenever new information indicates that it represents a potential hazard to the public health or the environment.

2. Since 1976, EPA has singled out 68 registered pesticides as potential health hazards, but has initiated RPAR's on only 36 of them. As of June 1984, EPA still had not completed action on 10 of the 36.

3. EPA initiated no RPAR's at all between April 1981 and March 1984 because of (1) the amount of work involved in completing the large number of RPAR's initiated in 1976-1977; (2) a 1980 Congressional amendment which required EPA to perform additional risk assessments before initiating RPARs; and (3) a reduction of staff available to work on RPAR's from 85-100 people in 1980 to only 22 in 1984.

4. EPA also changed its procedures with respect to initiating RPAR actions in apparent violation of its own regulations. While the regulations provide that an RPAR shall be initiated whenever any of the RPAR risk criteria are met or exceeded, EPA decided to change its policy and complete an entire Registration Standard before initiating an RPAR, even if it determined that one of the risk criteria had already been met.

5. EPA's experience with ethylene dibromide (EDB) exemplifies the extent to which the RPAR process is fraught with difficulties. For example, it took almost 10 years from the time the National Cancer Institute (NCI) preliminarily reported to EPA its finding that EDB produced cancer in rats and mice, and almost 7 years

from the time regulatory action data, including and the Department but no decision.

6. Economic footdragging an RPAR, rather than of the pesticide.

7. Former EP Substances, Dr. delay on EDB. Todhunter's offcally disappear 1983.

8. While inter they must respect time constraints can, and frequently.

9. During the vate meetings with State agencies, official memoranda Congress nor the what information made at or as a

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³³ Hearings, June 7, 1984.

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from the time EPA initiated its RPAR, for EPA to complete its regulatory action on EDB. As of April 1981, EPA had all the basic data, including the comments of its own Scientific Advisory Panel and the Department of Agriculture, to make a decision on EDB, but no decision was rendered at that time.

6. Economic and political considerations, as well as bureaucratic footdragging and inefficiency, caused most of the delay in the EDB RPAR, rather than legitimate scientific disputes about the dangers of the pesticide.

7. Former EPA Assistant Administrator for Pesticides and Toxic Substances, Dr. John Todhunter, was responsible for part of the delay on EDB. The EDB regulatory package was transmitted to Dr. Todhunter's office for approval in the summer of 1982 and inexplicably disappeared until after his departure from EPA in March 1983.

8. While interested parties are given explicit deadlines by which they must respond to proposed RPAR actions, there are no such time constraints on EPA for completing an RPAR and such actions can, and frequently do, drag on indefinitely.

9. During the RPAR on EDB, EPA officials had numerous private meetings with registrants of EDB products, other Federal and State agencies, and affected user groups. Generally there were no official memoranda of such meetings and without them neither the Congress nor the public knows who was present, what occurred, what information was presented, or whether any decisions were made at or as a result of the meetings.

10. Although fumigation of citrus represented a relatively small percentage of total EDB usage, EPA officials were especially solicitous about the effect of their proposals on the Florida citrus industry and that industry's Japanese market. In part because of the latter concern, EPA revised its proposed regulation to postpone the phase out of EDB on citrus from July 1983 to July 1985.

11. A potential conflict of interest occurred during the EDB deliberations when EPA contracted with Mr. Donald Lerch to advise it on the consequences of its proposed phase out of EDB on the Florida citrus industry's Japanese market. At the same time Mr. Lerch worked with a multitude of agribusiness interests and was on an annual retainer to the Japanese Government to counsel them on agricultural issues. Coincidentally, Dr. Todhunter, who approved the hiring of Mr. Lerch, entered into partnership with Mr. Lerch nine months after leaving EPA in order to "expand the firm's capability in handling problems related to registration and use of crop and food chemicals for both users and producers."

12. Even so, Mr. Lerch's report on his consultantship was of questionable value, since it appeared to overstate the potential Japanese reluctance to accept irradiated citrus fruit and ignored the fact that Japan was the first country in the world to commercially irradiate food on an industrial scale.

13. While EPA delayed regulatory action on EDB because of economic questions regarding the small-volume citrus fumigation use, its use as a soil fumigant (which accounted for 90 percent of total pesticidal usage) began to cause serious ground water contamination problems.

14. Most of the ground water contamination in Florida was due to the injection of amounts of EDB far exceeding the EPA-approved labeling into the soil surrounding citrus groves. Although the treatment was not in accordance with EPA labeling it was done pursuant to a U.S. Department of Agriculture manual. USDA either failed to warn the Florida Department of Agriculture that EPA labeling took precedence over its manual or the Florida Department of Agriculture ignored it.

15. Shortly after EPA's interim EDB regulatory actions on September 30, 1983, which included an emergency suspension of the soil fumigation use of EDB, and proposed cancellation of the uses for spot fumigation of grain mills and fumigation of stored grain, the State of Florida and other parties began discovering high levels of EDB residues in processed grain products.

16. Based on data from the Food and Drug Administration, several states, the American Bakers Association and the Grocery Manufacturers Association, EPA (1) suspended all uses of EDB to fumigate grains and grain milling equipment, (2) issued guidelines for maximum permissible levels of EDB in raw grains, processed grain products, and ready-to-eat products, and (3) initiated a rulemaking to terminate the exemption from the tolerance requirements for EDB on grain products.

17. EPA did not determine states' legal authorities and resources before issuing guidelines recommending maximum permissible levels for EDB; this resulted in serious problems for some states. Most states adopted EPA's standards; however, some adopted EPA's standards with variations, some adopted more rigorous standards, and some did not adopt any standards at all. As a result, there was no assurance that citizens of different states received equal protection, or that states which failed to adopt standards would not become dumping grounds for contaminated grain or grain-based products removed from states which did adopt standards.

18. By issuing such guidelines, EPA precluded some states from issuing more restrictive standards since some states are prohibited by state law from adopting standards which are more stringent than Federal standards.

19. In 1956, EDB was exempted from pesticide tolerance requirements for use in grain fumigation because it was believed that the pesticide was dissipated during the milling and baking processes. Despite numerous findings—as early as 1969—that EDB did, in fact, survive in finished food products, EPA took no action to revoke the exemption until 1984—a full fifteen years later.

20. Carbon tetrachloride and methyl bromide have been approved as alternatives to EDB; however, both these pesticides are still undergoing RPAR reviews and questions about their safety have not been resolved.

21. EPA initiated a special review (previously referred to as Rebuttable Presumption Against Registration) of dicofol on the basis that it was contaminated with DDT—a substance that had been banned by EPA since 1972 as an unreasonable risk to the environment. Dicofol was not included in the 1972 ban because the DDT and related compounds in it were "inert" as opposed to active ingredients. Because almost 300 active pesticide ingredients are also

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included as "inert" ingredients in other pesticides, it is likely that there are other cases where dangerous or potentially dangerous pesticides have been overlooked because they were considered "inert" ingredients.

22. Companies' confidential statements of formula always showed that DDT was present in dicofol. EPA only stumbled across this fact in 1979 during a Registration Standards review unrelated to DDT.

23. EPA's own regulations require it to initiate an RPAR when it finds that a registered pesticide may pose an unreasonable risk to man or the environment. However, EPA did not initiate an RPAR in 1979, when dicofol was "discovered" to contain DDT, which had been banned as an unreasonable risk to the environment. EPA's explanation for not doing so was that it wanted to complete the Registration Standard process in case there were any additional RPAR triggers for dicofol.

B. REREGISTRATION OF OLDER PESTICIDES

1. The Committee found serious lags in EPA's efforts to reregister older pesticides as required by the 1972 amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The Committee found that between 1972 and the end of fiscal year 1983, EPA had issued registration standards for only about 64 of 600 chemicals subject to that requirement. Even if EPA maintains its currently "expedited" pace of 25 standards per year it would not complete the standards for all 600 until the year 2005.

2. It is important to note that issuance of a registration standard does not complete reregistration of a pesticide; it only identifies data gaps which must be filled before reregistration can occur. By April 1983—when a District Court case interrupted the process—EPA had reregistered only 70 pesticide products representing 4 active ingredients. Even if the Court had not interrupted the process, by March 1984 EPA would have completed action on only 430 products, or less than 1 percent of the 50,000 registration subject to the reregistration requirement.

3. EPA's situation regarding reregistration of pesticides is somewhat analogous to that faced by FDA when it was required by law to review all new drugs which had been approved between 1938 and 1962 to determine whether they met new and tougher standards. FDA accomplished that review by contracting with the National Academy of Sciences/National Research Council, which utilized the resources of the nation's universities and colleges through its boards and committees. Once the NAS/NRC committees had completed their assessment of the scientific data, FDA was able to proceed with regulatory proposals.

4. EPA's Data Call-In program also is not proceeding as quickly as it should. The program is intended to assure that necessary data from needed long-term testing (2-4 years) are available or well underway before the pesticide is reassessed for reregistration. As of September 1983, EPA had issued Data Call-In notices for only about 165, or about 28 percent, of the 578 active pesticide ingredients involved in the program. If EPA continues its present rate of

75 Data Call-Ins per year it could not complete the Call-Ins before 1989.

5. EPA has not sufficiently coordinated its Data Call-in, Registration Standard, and RPAR programs to assure that situations involving the greatest potential risks receive priority consideration and expedited action, if necessary. In some cases, EPA has initiated Data Call-Ins on pesticides which are already in the RPAR process while in other cases it has delayed initiating RPAR action on a pesticide because the entire Registration Standard process had not been completed, even though an RPAR trigger had been identified.

C. EMERGENCY EXEMPTIONS

1. The Committee found that EPA's virtual wholesale approval of exemptions raises questions about the legitimacy of many "emergency" situations. Between 1978 and 1982 the number of emergency exemptions increased from 165 to 727 per year—a four-fold increase and a 45 percent annual growth rate.

2. During fiscal year 1983, (1) Federal and state agencies declared about 116 "crisis" exemptions; (2) EPA granted all 49 of the USDA Animal and Plant Health Inspection Service's requests for quarantine exemptions; and (3) EPA granted 379 state requests for specific exemptions, while denying only 50.

3. An EPA audit of the emergency exemption program showed that there were circumstances where (1) no real emergency existed; (2) the exemption was a circumvention of regular registration requirements; and (3) a more aggressive program for approval of minor pesticide uses could have eliminated the need for many such exemptions. The Subcommittee's investigation confirmed these findings and showed other problems in the exemption program as well.

4. EPA has allowed exemptions for unregistered and/or dangerous pesticides in situations where registered or less dangerous pesticides were available for controlling a pest outbreak.

5. In fiscal year 1983, EPA granted exemptions to 28 states to use the unregistered pesticide Larvadex to control flies in poultry houses, even though the fly problem was recurring and predictable. While users preferred Larvadex because of its convenience, there were 7 or 8 alternatives to the chemical.

6. A June 1983 report from the National Toxicology Program at the National Institutes of Health showed that Melamine, a metabolite³⁴ of Larvadex, caused cancer in laboratory rats and, subsequently, EPA temporarily revoked the emergency exemptions it had granted to the 28 states.

7. Despite EPA's revocation, two states invoked crisis exemptions to use Larvadex or its chemical equivalent. While EPA expressed displeasure with both states' arbitrary actions, it approved one state's use of Larvadex in poultry houses because EPA and FDA had concluded that the benefits of Larvadex outweighed the risks.

8. Despite the Delaney Anti-Cancer Clause,³⁵ EPA proposed a food additive regulation that would permit Larvadex in poultry

feed and in process. An FDA interpretation was allowed if the caution was heeded.

9. Less than a year after the hearing, EPA announced that it was granting agency exemptions on a conditional registration basis. The registrations were issued for 18 months or issue for 18 months if data was received.

10. EPA granted exemptions for the use of Mesurol. EPA granted exemptions for Mesurol to prevent outbreaks of fly which were granted in 1979 to 13 in 1983. It had been granted and was an unregistered pesticide because no other alternative was available for Mesurol in controlling fly.

11. The Committee's investigation of the exemptions submitted by three states. In addition, an Office of Pesticide Regulation found that pesticides for the states' requests were not cases, actually were not. The OPP at the time of the exemption, the only one granted and the number of exemptions.

12. One state did not request an emergency exemption. It merely sent a letter to EPA in the previous year's application.

13. During fiscal year 1983, EPA granted exemptions for downy mildew and other diseases. These exemptions were granted on questions regarding the use of pesticides.

14. The Subcommittee found that for fiscal year 1983, EPA required detailed information on exempted treatments. EPA reviewed the fiscal year 1984 budget.

15. Because of concerns about the use of Larvadex to circumvent the hearing in January. Based on those hearings, the subcommittee's investigation of the agency testimony on exemption regulation.

³⁴ A metabolite is a breakdown product of a chemical.

³⁵ Federal Food Drug and Cosmetic Act, Section 409(c)(3)(A).

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feed and in processed poultry. In taking this position, EPA adopted an FDA interpretation that cancer-causing food additives could be allowed if the cancer risk was estimated to be less than 1 in a million.

9. Less than a month after the Subcommittee's June 7, 1984 hearing, EPA announced that it was revoking the existing emergency exemptions for Larvadex, would defer a final decision on the conditional registration of Larvadex, and would not establish tolerances or issue food additive regulations for it until additional test data was received from the applicant.

10. EPA granted about 30 specific exemptions to 19 states for the use of Mesurol. Eighteen of the 30 exemptions were for use of Mesurol to prevent birds from eating grapes. The number of states which were granted exemptions for that purpose increased from 4 in 1979 to 13 in 1982 and, as of July 1983, two such requests had been granted and 15 applications were pending. Although Mesurol was an unregistered pesticide, EPA granted the exemptions because no other alternatives were considered "as effective" as Mesurol in controlling the problem.

11. The Committee found that there is questionable involvement by pesticide companies in the exemption program. The Subcommittee's investigation found remarkable similarity in the applications submitted by three different states for use of Mesurol on grapes. In addition, an Office of Pesticide Programs audit of the programs found that pesticide companies provided to the states information for the states' requests for emergency exemptions and, in some cases, actually wrote states' applications for emergency exemptions. The OPP audit also noted that there were cases where more than one state submitted a virtually identical request for an exemption, the only difference being the number of acres to be treated and the number of pounds of pesticides to be used.

12. One state didn't even bother to submit a detailed application for an emergency exemption to use Mesurol on grapes in 1983, but merely sent a short letter requesting an exemption based on the previous year's application. EPA approved the application.

13. During fiscal year 1983, EPA issued about 36 specific exemptions or amendments thereto for the use of Metalaxyl to control downy mildew and other diseases on a variety of garden products. These exemptions were granted even though there were unresolved questions regarding the cancer-causing potential of the pesticide.

14. The Subcommittee's review of EPA's emergency exemptions for fiscal year 1983 revealed that almost none of the files contained the required detailed monitoring reports on usage during the exempted treatments. EPA maintained that it was just beginning to review the fiscal year 1983 reports on exemption treatments in fiscal year 1984 because of inadequate manpower.

15. Because of concerns that the exemption procedure could be used to circumvent the full registration process, EPA held public hearings in January 1984 on emergency exemption procedures. Based on those hearings, as well as a 1979 report from a Congressional committee and an internal audit of the exemption program, the agency testified that it will propose a revision of its emergency exemption regulations in early 1985.

D. QUALITY OF DATA SUPPORTING PESTICIDE REGISTRATIONS

1. In 1976, EPA learned that Industrial Biotest Laboratories (IBT)—one of the largest independent laboratories used by the pesticide industry to support pesticide applications—was submitting falsified data to support registrations both in this country and in Canada.

2. Even after EPA discovered the problems at IBT it did not move expeditiously to correct the situation and obtain replacement studies. Over a 5-year period EPA and the Health Protection Branch (HPB) of the Canadian Department of Health attempted jointly to validate more than 2,000 studies which had been submitted by IBT. It was found that more than 90 percent of the studies which had been submitted in support of pesticide registration applications were not valid.

3. EPA experienced problems with the validations performed by HPB Canada and determined that many of the studies which Canada had declared valid, in fact, were not.

4. Summary statistics in 1983 showed that of the 642 studies reviewed by EPA, only 81 (or 13 percent) were determined valid; but of the 479 studies reviewed by Canada, 133 (or almost 28 percent) were determined to be valid by HPB.

5. EPA did not know how many Canadian determinations were revalidated or how many remained to be revalidated or evaluated because EPA decided to deter further review of the Canadian validations.

6. The universe of IBT studies which were of concern to EPA dropped from more than 2,000 studies to 724 studies because EPA arbitrarily decided to eliminate acute toxicity, fish and wildlife, and other environmental studies as well as other studies which the agency deemed "irrelevant" to the kinds of health effects it was interested in.

7. It took EPA seven years to formally publish information on the scope of the IBT problem. This lengthy delay caused unnecessary confusion and uncertainty among pesticide manufacturers, registrants, users and the general public.

8. Eventually, EPA sent formal 90-day response letters to the registrants of only 8 chemicals informing them which IBT studies required replacement.

9. In the case of the pesticide santophen, 202 registrants were sent 90-day response notices informing them that 9 studies performed by IBT were invalid and would have to be replaced. Two major producers of santophen agreed to jointly perform the replacement studies after they negotiated with EPA to reduce to three the number of studies which required replacement and an extension of the deadline for submitting two of the required studies.

10. As of March 1984, of the 392 studies which required replacement, only 243 (or 62 percent) had been accepted by EPA, were under review at EPA, or were in progress at the company. However, EPA decided to defer requesting the remaining 149 (or 38 percent) of the studies which required replacement until they came up for review in the routine Registration Standards or Data Call-In programs. Included are 38 studies which will not be involved in those programs until after late 1985 or 1986.

11. In some cases, laboratories submitted studies to a company to substitute for their own.

12. EPA attempted to inspect some of the studies to determine whether they were valid. In some cases, to audit studies are actually conducted. EPA check procedures in laboratories only on a case-by-case basis.

VII

On the basis of the information that there are a number of EPA's pesticide management activities which are inadequate to reach specific conclusions, it is necessary to add to the information.

A companion report on Environmental Relationships and Conclusions and of the Food and Drug Administration's program. EPA's program. bring about necessary pesticide program.

A. REBUTTAL

The Committee's intended purpose was to determine whether to restrict its use, which continued use of risks to the environment, mutagenesis, and carcinogenesis.

Out of 68 registered RPAR candidates, only 36 had been replaced by 1984. Moreover, in 1981 and March 1984, the EPA staff was in 1984. However, these personnel made all reductions in the number of studies submitted by registrator Anne Gorsuch. Reduction and then size the RPAR program.

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11. In some cases, EPA intends to allow studies from other laboratories submitted by other companies to negate the need for a company to submit a valid study to replace an invalid IBT study.

12. EPA and FDA have a joint program under which they attempt to inspect about 40 laboratories each year to determine whether they follow "good laboratory practices," and, in a few cases, to audit specific studies to see whether the conclusions in the studies are actually supported by the raw data. This is only a spot check procedure and, at best, provides for visitation of all 400 laboratories only once every ten years.

VIII. CONCLUSIONS AND RECOMMENDATIONS

On the basis of the foregoing findings, the Committee concludes that there are a number of serious problems in the administration of EPA's pesticide registration activities which require immediate management attention. If such attention is not forthcoming or is inadequate to remedy the deficiencies spelled out in the following specific conclusions and recommendations, the Congress may find it necessary to address these problems legislatively.

A companion report prepared by the Subcommittee on Intergovernmental Relations and Human Resources will include findings, conclusions and recommendations regarding the pesticide activities of the Food and Drug Administration and its coordination with EPA's program. It is the Committee's hope that these reports will bring about necessary improvements in the Federal Government's pesticide programs.

A. REBUTTABLE PRESUMPTION AGAINST REGISTRATION (RPAR)

The Committee concludes that the RPAR process is not achieving its intended purpose of providing an expedited decision by EPA on whether to remove a registered pesticide from the market, or to restrict its use, when new information comes to light indicating that continued use of the product might present certain unreasonable risks to the environment or public health, such as cancer, birth defects, mutagenesis or other serious adverse effects.

Out of 68 registered pesticides singled out by EPA as potential RPAR candidates since 1976, the agency initiated RPAR actions on only 36 and had failed to complete action on 10 of these by June of 1984. Moreover, no RPAR actions were initiated between April 1981 and March 1984, and this hiatus coincided with a reduction in the EPA staff working on RPAR's from 85-100 in 1980 to only 22 in 1984. However, the Committee could not determine whether these personnel reductions were a normal consequence of the overall reductions instituted during the regime of former EPA Administrator Anne Gorsuch Burford, or represented a disproportionate reduction and therefore reflected a conscious decision to de-emphasize the RPAR program.

In any event, the Committee recommends that the EPA Administrator take such actions as are necessary to increase the staff resources devoted to the RPAR (Special Review) process to the point that expeditious decisions can be made on all registered pesticides which any available information indicates may constitute an unreasonable risk to man or the environment.

However, the Committee must also conclude, on the basis of its findings regarding EPA's performance with respect to the specific RPAR reviews on EDB and other potentially dangerous pesticides, that the root causes of the problems in the RPAR process go much deeper than the cutbacks in personnel. The fact that not a single RPAR action was initiated during a three year period, although there was no dearth of candidates, indicates that there has been great reluctance to initiate the "expedited" RPAR decision-making process. This was confirmed by testimony from the Director of EPA's Office of Pesticide Programs³⁶ that EPA had changed its procedures so that the agency would not initiate an RPAR proceeding immediately upon the discovery of an RPAR trigger (e.g. evidence of a potential to cause cancer, reproductive disorders, mutagenesis, chronic wildlife effects, etc.), but rather would wait until the much slower registration standards procedure was completed in order to determine all other potential adverse effects.

This is in clear violation of EPA's own RPAR regulations³⁷ which state that "a rebuttable presumption *shall*³⁸ arise" if a pesticide meets or exceeds such triggers, and defeats the very purpose of the RPAR process to expedite decisions where the continued use of a pesticide may constitute an unreasonable risk to man or the environment.

In order to provide the highest degree of public health protection from pesticides which may pose unreasonable risks, the Committee recommends that EPA adhere stringently to its RPAR regulations by promptly initiating an RPAR proceeding whenever any one of the "trigger" criteria included in the regulations is met with respect to any registered pesticide.

Even after EPA decides to initiate an RPAR proceeding on a particular pesticide, the process does not achieve its intended purpose of expediting a final decision on the product's status. For example, almost 9 years elapsed from the time that the National Cancer Institute reported to EPA its preliminary finding that EDB caused cancer in laboratory animals, before EPA completed its RPAR action on EDB. Moreover, EPA witnesses acknowledged that the RPAR process has not proven to be as expeditious as expected and has averaged between 4 and 5 years for completion.³⁹

On the basis of the facts disclosed during the Subcommittee's hearings on the RPAR proceeding on EDB, the Committee must conclude that economic and political considerations and bureaucratic footdragging and inefficiencies caused most of the delay in the RPAR on EDB, rather than legitimate scientific disputes about the dangers of the pesticide. Although the law and regulations set specific time limits for parties affected by an RPAR notice to submit rebuttal evidence and for the Secretary of Agriculture and EPA's Scientific Advisory Panel to submit their views, there is no over-all time limit within which EPA must complete the RPAR action. Thus, in the case of EDB, EPA continued to accept additional information and arguments from these sources long after the

³⁶ Hearings, June 7, 1984.

³⁷ 40 CFR, 162.11(a)(3).

³⁸ Emphasis added.

³⁹ Hearings, September 26, 1983.

deadlines had passed. EDB represented. Moreover, much of the time was spent in sessions with

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deadlines had passed and much of it had no relation to whether EDB represented an unreasonable risk to man or the environment. Moreover, much of this activity took place in closed door negotiating sessions with no official record being kept of what took place.

In order to remedy these deficiencies and to improve the timeliness, integrity and effectiveness of the RPAR process, the Committee recommends that:

EPA adhere stringently to the established time limits for submission of rebuttal evidence and views of the Secretary of Agriculture and the Scientific Advisory Panel;

An over-all time limit be established for the completion of an RPAR action with milestones for the accomplishment of each step in the process (e.g. issuance of Position Documents 1, 2, 3, and 4).

After publication of the initial RPAR notice, a record be kept of all meetings with interested parties specifying who was in attendance, what occurred, and what decisions or agreements, if any, were reached.

The Committee found that a recommended final decision document on EDB, which had been forwarded to the Assistant Administrator for Pesticides and Toxic Substances for his approval and signature, inexplicably disappeared. Accordingly the Committee must conclude that there is not an adequate tracking system for RPAR decision documents. The Committee therefore recommends that an appropriate tracking system be established, with milestones, to expedite processing, fix responsibility for decision making at each level and each step of the process, and create an audit trail for reconstruction of the decision-making process.

The Committee concludes that inordinate delays in completion of the RPAR action on EDB resulted from:

Delaying final action on all of the multiple uses of EDB until disagreements regarding one relatively small-volume use (citrus fumigation, 10% of total usage) were resolved, even though agreement had already been reached on what to do about the other uses, and despite the fact that virtually no citrus fruit domestically produced and consumed was being fumigated with EDB.

Concern over the possible reaction of the Japanese Government, which required the use of EDB on all imported citrus in order to prevent fruit fly entry, and the economic consequences on the Japanese market for U.S. citrus of banning the use of EDB; and

Concern over the economic consequences of banning EDB citrus fumigation for foreign countries which exported citrus to the U.S.

In the event that similar situations should arise with respect to future RPAR proceedings, the Committee recommends that:

In the case of multiple uses of a pesticide, EPA proceed with final action as agreement is reached on each separate use;

Final RPAR decisions be based solely on assessment of the risks and benefits of usage within the U.S.;

The use of a banned pesticide on products for export be permitted only when it is required by the Government of the importing country and only under EPA supervision; and

The Committee concludes that EPA is not achieving in a timely manner the Congressionally mandated reregistration of older (pre-1972) pesticides, to assure that they meet current safety requirements, and that the agency will not complete even the first phase of the task until the next century, if it continues to perform at its current pace. Moreover, in view of the limited personnel resources available in relation to the magnitude of the task, and the prospect of continuing budgetary restraints during the foreseeable future, the Committee questions whether EPA can ever complete the task without outside assistance. The Committee believes that it poses a danger to the public health, and is patently unfair, to allow older pesticides to remain on the market indefinitely without having to meet the same safety standards imposed upon new pesticides.

The Committee also concludes that EPA's Data Call-In program, which is a prerequisite for reregistration, is not proceeding at an expeditious pace. The Committee recommends that after making arrangements for outside scientific assistance, EPA publish in the Federal Register a general Data Call-In for all pesticide registrations approved prior to enactment of the 1972 FIFRA amendments, calling for submission of all data currently required in new pesticide registration applications, if such data have not already been submitted. EPA can then utilize its outside scientific assistance to review the data received to determine its completeness and validity, to identify additional studies needed, and to make a human health risk assessment, and possibly a risk/benefit analysis. EPA can then use this information in reaching its risk management regulatory decisions.

The Committee also concludes that the Data Call-In, Reregistration, and RPAR programs have not been sufficiently coordinated to assure that situations involving the greatest potential risks receive priority consideration and expedited action, if necessary. Compliance by EPA with the immediately preceding recommendation regarding Data Call-in should alleviate that part of the coordination problem regarding coordination of the Data Call-In and Reregistration programs. However, the Committee recommends that any time that the Data Call-in or Reregistration processes identify a situation involving a possible RPAR "trigger" (e.g. evidence of a potential to cause cancer, reproductive disorders, mutagenesis, chronic wildlife effects, etc.) that the pesticide in question be immediately referred to the RPAR program for expedited action.

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⁴⁰ Hearings, June 7,

C. EMERGENCY EXEMPTIONS

The finding that a four-fold increase occurred in the number of emergency exemptions approved annually by EPA between 1978 and 1982 raises serious questions as to whether the purpose of some such "emergency" exemptions may, in fact, have been simply to circumvent the normal pesticide registration process. A recent audit of the emergency exemption process by EPA confirmed that this was the case.

EPA officials acknowledged the existence of this problem during the hearings and stated that the agency would propose revisions in the emergency exemption regulations in early 1985.⁴⁰ However, the findings that EPA has approved a very high percentage of applications for emergency exemptions; seldom revoked such exemptions; unquestioningly renewed such exemptions from year to year; and granted emergency exemptions for the use of unregistered pesticides in situations where registered and/or less dangerous alternatives were available, leads the Committee to conclude that EPA's procedures for granting and monitoring emergency exemptions for unregistered uses of pesticides are inadequate.

In order to halt the wholesale granting of emergency exemptions and the utilization of such exemptions to circumvent the normal pesticide registration process, and to improve EPA's procedures for approving and monitoring such exemptions, the Committee recommends that EPA:

- Expedite its proposed revision of the emergency exemption regulations so that the process can be completed before the start of the 1985 growing season;

- Approve no further exemptions for totally unregistered pesticides, if registered and/or less dangerous alternatives are available;

- Institute more stringent requirements of proof that a true emergency exists before approving an application for exemption;

- Reject any exemption application for which there is evidence or reason to believe that it constitutes an attempt to circumvent the normal pesticide registration requirements;

- Reduce the incentives for using the emergency exemption procedure as a circumventational device by developing a better minor-use program, as recommended in the agency's own audit of the emergency exemption program;

- Seek public comments on applications for emergency exemptions, whenever possible, before they are approved;

- Improve the monitoring of pesticide operations under emergency exemptions in order to assure that a legitimate emergency exists and that all conditions included in the permit are complied with; and

- Assure that State Departments of Agriculture and other relevant agencies are aware that whenever a pesticide use recommended in manuals published by the U.S. Department of Agriculture deviates from the safety requirements in the EPA approved labeling, as was the case in the use of EDB as a soil

⁴⁰ Hearings, June 7, 1984.

fumigant for citrus fruit trees, the EPA labeling shall take precedence unless an exemption is obtained from EPA.

D. QUALITY OF DATA SUPPORTING PESTICIDE REGISTRATIONS AND EPA'S REVIEW AND INSPECTION PROCEDURES

The Committee has reason to doubt that EPA's review and evaluation of the scientific studies submitted in support of pesticide registration applications, and its audits and inspections of the laboratories in which they are conducted, are adequate to assure that such studies are valid and of sufficiently high quality to meet the standards for proof of safety imposed by the law and regulations. This conclusion is based largely on the findings in the Subcommittee's review and hearings regarding the falsification of such data by Industrial Biotest Laboratories (IBT), one of the largest independent laboratories employed by pesticide manufacturers to conduct studies to be submitted in support of pesticide registration applications. However, because of the magnitude of the problem—upon re-evaluation, only 10% of over 2,000 studies were deemed to be valid, although all had previously been accepted by EPA—and the fact that it went undetected by EPA for many years, there can be no assurance that other, similar situations do not exist.

Moreover, it took EPA seven years to determine which of the IBT studies were invalid and, if so, whether they were essential to the approval of particular pesticide registrations and would therefore require replacement studies. Most of these essential studies still have not been replaced and many will not be required to be replaced for several more years, since they have been referred to the routine Data Call-In and Registration Standards programs.

This performance does not inspire confidence in the quality of EPA's review, evaluation and approval of pesticide registration applications. The Committee therefore recommends that:

The EPA Administrator immediately institute an internal review and evaluation of the agency's policies and procedures for and performance in reviewing, evaluating, and approving pesticide registration applications in order to identify areas which need improvement;

EPA consider requiring the submission of suitable copies of the raw data on all studies submitted in support of a pesticide registration application and cross-checking such data, at least on a spot basis, against the information included in the application in order to reduce the likelihood of falsification or misrepresentation of the results of such studies;

Steps be taken to improve the frequency and depth of EPA's inspection and auditing of pesticide testing laboratories, including the review of raw data and comparison to the reports on studies sent to EPA in connection with pesticide registration applications;

A priority system be established to select laboratories for inspection and audit, taking into account such factors as the volume of studies submitted in support of pesticide registration applications, evaluations of past performance, and other relevant factors; and that

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EPA take immediate steps to secure the replacement of all invalid studies by IBT Laboratories which are essential to meet any current requirement for any approved pesticide registration.

E. OTHER CONCLUSIONS AND RECOMMENDATIONS

On the basis of the Subcommittee's review and hearings regarding the pesticide EDB, the Committee concludes that there is a serious deficiency in existing law in that there is no provision to permit the Administrator of EPA to issue an immediate emergency revocation of a previously granted exemption from pesticide tolerance requirements, even if he finds that continuation of the exemption constitutes an imminent hazard to the public health. The Committee therefore recommends that appropriate committees of the Congress consider amending existing law to remedy this deficiency. The Committee also recommends that henceforth EPA initiate a revocation proceeding immediately upon learning that the basis for the exemption may no longer be valid, rather than waiting for a public health emergency to arise, as was the case with EDB.

The Committee also concludes on the basis of the EDB experience that EPA needs to improve its coordination with state agencies on pesticide enforcement actions. Because of EPA's inability to immediately revoke the EDB exemption from Federal pesticide residue tolerances, the agency issued suggested maximum residue levels to be enforced by the states without first obtaining their concurrence, or consulting with state agencies about the adequacy of their legal authority and resources for enforcement. This caused significant problems for some states.

The EDB experience also disclosed that there are weaknesses in EPA's procedures to prevent the use of existing stocks of a banned pesticide and to assure their proper disposal. EPA has the authority and funds to indemnify potential users who turn in previously purchased stocks of such pesticides. However, testimony at the Subcommittee's April 11, 1984 hearing on ground water protection indicated that EPA still had not announced any indemnification program for EDB even though its use as a soil fumigant had been banned more than 6 months earlier on September 30, 1983. Testimony at the same hearing indicated that approximately 15,000 gallons of EDB remained in the hands of Florida farmers and that some of it was being used illegally.⁴¹ The Committee therefore recommends that EPA take steps to expedite its pesticide indemnification procedures in order to bring about the rapid removal, and proper disposal of existing stocks of pesticides which have been banned.

The Committee recommends that EPA conduct a survey of approved pesticide registrations to determine the number of instances in which an active ingredient in one product is listed as an "inert" ingredient in another product, as was the case with DDT in dicofol. If the number of such instances is significant the Committee rec-

⁴¹ Transcript of hearings on Review of the Groundwater Protection Strategy of the Environmental Protection Agency, April 11, 1984, pp. 128-129.

ommends that EPA change its procedures to treat such ingredients as if they were active ingredients, even if they are listed as "inert."

In order to insure that the recommendations in this report are given due consideration, the Committee directs the Administrator to advise the Committee within 90 days of the issuance of this report of his views with respect to each recommendation made and any actions he has taken or plans to take for their implementation, or the reasons why he may feel that such actions are unnecessary or inappropriate.

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